

Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan

DECISION OF THE 33RD MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 02-06-2021

Item No. I. APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.

S.No	Name of Establishment	Director/Proprietor /partners	Cold Chain (Yes/No)	Decision
1.	M/s. United Medical, Mall Avenue, 54 Shahrah-E-Quiad-e-azam, Lahore.	Shoaib Rizwan Usmani	No.	Approved for storage of room temperature medical devices.
2.	M/s United Healthcare Inc, C-271, Ground Floor, Gulistan-e-Johar, Block 14, Karachi.	Muhammad Jawad Kashmiri	No	Approved for storage of non cold chain medical devices.
3.	M/s Global Dentel Supplies, C15, G1, Golden Tower, Block-10, F.B. Area, Karachi.	Muhammad Irfan	No	Approved for storage of non cold chain medical devices.
4.	M/s Avixx Healthcare, Office No. 04, 121/2-36-A-K, Area Korangi, Karachi.	Muhammad Rashid Khan Farkhanda Shaheen Maleeha Laj	No	Approved for storage of non cold chain medical devices.
5.	M/s East West Links, Shop No. 4-SD-23, Block B, North Nazimabad, Karachi.	Naeem Asghar Aleem	No	Approved for storage of room temperature medical devices.
6.	M/s. Ali sons, Room No. 37, 2 nd Floor, Luxmi Building M.A.Jinnah Road, Karachi Godown: KPT Plot No.30, West Wharf,	Mr. Habib Ali	No	Approved for storage of room temperature medical devices.

	Karachi.			
7.	M/s. Glo-Med, A-21/2 B1, KDA Scheme 1 (Ext), Stadium Road, Karachi	Muhammad Ejaz Mirza	No	Approved for storage of room temperature medical devices.
8.	M/s. Innovative Medical Solutions, 60-A S.M.C.H.S, Karachi.	Muzaffar Ali Issani	No	Approved for storage of room temperature medical devices.
9.	M/s Master Enterprises, Plaza No. 226-A, 3 rd Floor Sector C, Commercial Chambeli Block, Bahria Town, Lahore.	Irfan Khalil	No	Approved for storage of room temperature medical devices.
10.	M/s Lifespan Healthcare, Office No. 11, 7 th Floor, Gold Mine Plaza, 105-Ferozepur Road Lahore.	Muammad Faisal Muhammad Afzal	No	Approved for storage of non cold chain medical devices.
11.	M/s MH Pharma, Flat No. 1118, 11 th Floor, Eden Heights, 6 Main Gulberg, Jail Road, Lahore.	Muhammad Munir Iqbal Ghulam Haider	No	Approved for storage of room temperature medical devices.
12.	M/s Bio-Tech Services, 746 Shadman-1, Lahore.	Zahid Iqbal Ghauri	No	Approved for storage of room temperature medical devices.
13.	M/s Caretakers, 169-A, Block-B, B.O.R. Society, M.A. Johar Town, Lahore.	Mr. Akhtar Hussain	No	Approved for storage of non cold chain medical devices.
14.	M/s. Roys & Roys International, 1 st Floor Rehman Center-2, Service Lane Ring Road Near Askari-11, Lahore	Ijaz Naseer	No	Approved for storage of non cold chain medical devices.
15.	M/s Complete Medical Solutions, 85-J-1, Sunflower Society, Johar Town, Lahore	Mr. Arif Raza	No	Rejected as it was a residential facility and several home installations were seen throughout the

				<p>facility. The hygienic conditions were poor and there was dust all over the facility. The firm's management had not prepared any Site Master File, SOPs and any other related documents as required vide the checklist given above. The applicant did not have Drug Sale License. Technical staff such as pharmacist was also not employed, as informed by the management.</p>
16.	<p>M/s. RG Pharmaceutica (Pvt) Ltd, BF1-01-First Floor, Gate No. 1 Bahria Orchard, Main Raiwind Road, Lahore Godown: Plot No. 247, Sunder Industrial Estate, Raiwind Road, Lahore.</p>	Muhammad Naveed Butt	No	<p>Approved for storage of non cold chain medical devices.</p> <p>The Board also acceded the request of the firm and cancelled the establishment license (ELI-00485) already issued on 30-01-2020 to M/s RG Pharmaceutica (Pvt) Ltd, Office .703, Progressive Square, Block-6, P.E.C.H.S, Shahrach-e-Faisal, Karachi.</p>
17.	<p>M/s Commodities Sourcing Corporation, 18-Habib Park, Model Town, Link Road, Lahore.</p>	Mr. Shabbir Ahmed	No	<p>Rejected as the facility was inside a house located in a residential area. The room which was inspected for the purpose of grant of establishment license was located on the first floor. It was a small room</p>

				<p>measuring 13x9 feet approximately. Right outside the entrance to the room was an open drain. The walls of the room were full of seepage. No racks, pallets were installed. Fan or AC was also not installed. Two open windows were present in the room. The room was dusty and unhygienic. Paint work was not satisfactory. The room was being used as a store room and several households items were placed inside. The management informed that they do not have Drug Sale License, nor had they applied for the same. Relevant technical staff was also not hired/available. Documentation was poor. The SOPs were unauthorized and were not developed according to a proper format as required for developing SOPs.</p>
18.	M/s. Ayyan Molecular Products, Suit No. 16-B, 1 st Floor Chaubuji Center Multan Road, Lahore.	Wajahat Khan	Yes	Approved for storage of room temperature alongwith cold chain medical devices.
19.	M/s I.R.Scientific International, Office Suit Ho.54, M-2 Mezzanine Floor, P.E.C.H.S Block-2, Karachi.	Muhammad Rizwan Khan	No	Approved for storage of room temperature medical devices.

20.	M/s. ZI Enterprises, Office No. 6 Msezzanine Floor, Reshmeen Plaza unit 8, Latifabad, Hyderabad	Mr. Syed Salah Uddin	No	Approved for storage of non cold chain medical devices.
21.	M/s Easa Business Group, Plot C-98, Ground Floor, Block- D, Unit No.07, Latifabad, Hyderabad.	Syed Umair Ahmed	Yes	Approved for storage of room temperature alongwith cold chain medical devices.
22.	M/s Umer Trading Corporation, Plot No. 86-D, Unit No 8, Latifabad, Hyderabad.	Zubair Amir	No.	Approved for storage of room temperature medical devices.
23.	M/s. S& T Corporation, Banglow NO. B-56 unit NO. 2 Latifabad, Hyderabad Godown: Plot NO. A- 10-V, S.I.T.E Area, Hyderabad	Mr. Tariq Hafeez Shaikh	No.	Approved for storage of room temperature medical devices.
24.	M/s. Fresenius Medical Care Pakistan (Pvt) Ltd, Plot No. A6-A7, North Western Industrial Zone Port Qasim, Karachi.	Mr. Javid Nasir Quareshi Mr. Kwong Leung Tsang Mr. Lars Jandt Mr. Andreas Hendrik De Wit	No.	Approved for storage of non cold chain medical devices.
25.	M/s Endovision Enterprises, A-173, Block-3, Gulistan-e- Jauher, Karachi.	Shahbaz Orangzeb	No.	Approved for storage of non cold chain medical devices.
26.	M/s Tabros Pharma (Pvt) Ltd, Essa House 32-1-C, Block-6, P.E.C.H.S., Karachi. Godown Address: L-19-A-1, Sector-22, F.B Area, Karachi.	Muhammad Abdullah (CEO) Muhammad Yayha Essa	No.	Approved for storage of non cold chain medical devices.
27.	M/s Angels Enterprises, 70-L, P.E.C.H.S., Block 6, Karachi.	Mr. Jahanzeb Khan	No.	Approved for storage of room temperature medical devices.
28.	M/s City Links International, Plot No.	M/s Nasir Abbas	No.	Approved for storage of room

	1-6-J, 3 rd Floor, Block 6 P.E.C.H.S., Karachi.			temperature medical devices.
29.	M/s SleepEasy, Suite # 2 Plot SB-12, KDA Scheme 1A, Stadium Road, Karachi.	Saad Ahmed	No.	Approved for storage of non cold chain medical devices.
30.	M/s Rayan & Co, Office No. 241, Plot No. SE-5, Block M, Bhayani Shopping Centre, North Nazimabad, Karachi.	Syed Waqar Ahmed	No	Rejected as the firm has changed their establishment address. Firm is advised to apply afresh.
31.	M/s Daneen Pharma (Pvt) Ltd, Plot No. 27, sundar Industrial Estate, Sundar Raiwind Road, Lahore.	Ch.Muhammad Shahbaz Babar Ch.Muhammad Israr Sharif	No	Deferred. Panel has enclosed a letter from the firm wherein it is stated that they insufficient storage of handling medical devices as per required by the department, and now they are upgrading their storage space or change the location of warehouse to fulfill the requirements as per department.
32.	M/s Mediplex International (Pvt) Ltd., Flat No. 03, Block No. 16C, Malik Plaza, First Floor, F-8 Markaz, Islamabad.	Mr. Fazal Younas Mr. Rehman Younas Salarzai,	No	Rejected. The panel inspected the firm's premises on 15-04/2021. The firm was holding a small office but did not have any storage facility for the storage of medical devices as per checklist nor have any documentation/SOPs . Furthermore, firm did not have any qualified technical person to supervise the storage and distribution of the

				medical devices.
33.	M/s. ABA Enterprises ABA House Opposite A-4, Anwar Villas Phase 2, Hyderabad	Aijaz Ali	No	Approved for storage of room temperature medical devices.
34.	M/s International Trading Co, 64/S, P.E.C.H.S, Block 2, Karachi.	Muhammad Imran	No	Approved for storage of room temperature medical devices.
35.	M/s. Link Traders, Office No. 1&2 Mezzanine Floor, ahmed Trade Center, 2-B Commercial Area Nazimabad No. 2, Karachi	Muhammad Asim	No	Approved for storage of non-cold chain medical devices.
36.	M/s. Fartal Pharmaceuticals, Plot No. 9, Street No. 1 Model Colony , Karachi.	Dr. Fareeha Talha	No	Approved for storage of non-cold chain medical devices.
37.	M/s. Saim Medical, M- 05, Plot No. ST # 14, Mezzanine Floor Wondor Tower, Block- 11, Gulshan-e-iqbal Karachi.	Adnan Hashmat	No	Approved for storage of non-cold chain medical devices.
38.	M/s. MKM Pharmaceuticals, Office No. 303, Progressive Square, Block 6, PECHS Shahra-e-Faisal Karachi	Mirza Zubair Khaild	Yes	Approved for storage of room temperature alongwith cold chain medical devices.
39.	M/s. Tech Access International, Office No. M-06, Mezzanine Floor Wonder Tower Block-11, Gulsha-e- Iqbal, Karachi	Waseem Hashmat	No	Approved for storage of non-cold chain medical devices.
40.	M/s Imperial Traders, 7/A, Block-B Unit No. 10, Latifabad, Hyderabad.	Mr. Farrukh Atique Rajput	Yes	Approved for storage of room temperature alongwith cold chain medical devices.
41.	M/s RTJ Enterprises, B/207, Block C Unit No. 02, Latifabad Hyderabad	Mr. Muhammad Rehan Rajput	Yes	Approved for storage of room temperature alongwith cold chain

				medical devices.
42.	M/s. Medi Hope Enterprises, 38/1, Rose Line # 4 New Lalazar Morgha, Rawalpindi.	Mr. Musarrat Javaid Janjua	No	Approved for storage of room temperature medical devices.
43.	M/s Rose International Scientific, 1 st floor, Suit No. 1, Khan Plaza, main Peshawar road, Rawalpindi Cantt, Rawalpindi.	Mr. Sabir Hussain	No	Rejected. Panel inspected the premises of M/s Rose International Scientific on 31-05-2021, firm just owned an office at the applied premises but did not have storage facility for the storage of medical devices on the said premises. Firm advised to arrange proper storage facility as per checklist and applied again.
44.	M/s Intek Corporation (Pvt) Ltd, Office No. 501, Kohistan Tower, Opp AFIC, The Mall, Rawalpindi. Godown Address: Office No.502, Kohistan Tower, Opp AFIC, The Mall, Rawalpindi.	Irfan-ul-Azeem Arain Haseeb Ahsan Raja	Yes	Approved for storage of room temperature alongwith cold chain medical devices.
45.	M/s. Faizan Enterprises, Godwon No. 2 Plot No. 5, Com Row F, Sector 16, Gulshan –E-Kaneez Fatima Karachi.	Muhammad Faizan	No	Approved for storage of non cold chain medical devices.
46.	M/s Pak Medical Company, D-110/1, Block 4, F.B. Area, Gulberg Town, Karachi Central.	Iffat Asif	No	Approved for storage of non cold chain medical devices.
47.	M/s Hussan Trader, Shop # C-25 A, Quetta Wala Market, Kutchi Gali No.1, 1/2, Marriot	Ghulam Muhammad	No	Approved for storage of room temperature medical devices.

	Road, Karachi.			
48.	M/s Atlas Enterprises, 3-Talpur Building, 1 st floor , Near Dow Medical College, M.A.Jinnah Road, Karachi.	Asif Raza	No	Approved for storage of room temperature medical devices.
49.	M/s Sindh Trading Corporation, 217-219, Prince Center, Preedy Street, Saddar, Karachi.	Muhammad Jawaid Sheikh	No	Approved for storage of room temperature medical devices.
50.	M/s. Currax Traders, House NO. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway Pakistan, Rawalpindi	Mr. Amjad Khan	No.	Approved for storage of room temperature medical devices.
51.	M/s ANC Impex International (Pvt) Ltd, House No. D-151. Housing Scheme No. 1, Gujar Khan, District Rawalpindi.	Mr. Naveed Javed	No.	Approved for storage of room temperature medical devices.
52.	M/s HA Shah & Sons, Office No. 3, 3 rd Floor, Saddar Begumk plaza, 109-W, Jinnah Avenue Blue Area, Islamabad.	Syed Waqar Ali Bukhari Syed Mushraf Hussain Bukhari Syed Zulfiqar Ali Bukhari	Yes	Approved for storage of room temperature alongwith cold chain medical devices.
53.	M/s. Pakistan Surgical Distributors, Office No. 1, First Floor Ehtisham Chamber, Crossing Gumpat Road, Lahore.	Muhammad Mudasar Hayat Khan	No	Approved for storage of non cold chain medical devices.
54.	M/s. Medic Ally (Pvt) Ltd, 403-Nishtar Block Allama Iqbal Town , Lahore	Sajjad Hussain	No	Approved for storage of non cold chain medical devices.
55.	M/s. Medipak Limited, 132/1, Industrial Estate, Kot Lkhat Lahore	Dr. Khalid Javid Ch. Naveed Khalid Ch. Naureen Khalid Nasir Javed Ch. Dr. Khalida javaid Nosheen Khalid	No	Approved for storage of room temperature medical device s.

56.	M/s. MediServe, House No. 21-A, Q Block, Gulberg-II, Lahore	Afzaal Iqbal	No	Approved for storage of non cold chain medical devices.
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Item No.II. APPLICATIONS FOR SITE VERIFICATION FOR ESTABLISHMENT OF A MANUFACTURING UNIT OF MEDICAL DEVICES.

Case No.1.

Decision: The Board approved the site for establishment of manufacturing unit of medical devices of DKT Pakistan (Pvt) Limited, Near Pul Dingro, Sargodha Road (Ex Coca Cola Factory), Faisalabad.

Case No.2.

Decision: The Board approved the site for establishment of manufacturing unit of medical devices of M/s Iffa Industries, 6-KM, Depalpur Road, Link 34/21 Road, Near Grid Station, Okara.

Case No.3.

Decision: The Board approved the site for establishment of manufacturing unit of medical devices of M/s Orbit Natural (Pvt) Ltd, 22-KM, Adyala Road, Rawalpindi.

Item No.III. POST LICENSE VARIATIONS.

Case No.01.

M/s Nisa SF Limited, 10-KM, Muridke, Sheikhpura Road, District Sheikhpura has requested for approval of change of their Quality Control Incharge in their ELM-0001 issued on 03-08-2018 as per detail given below:-

Existing Quality Control Incharge	Proposed Quality Control Incharge
Mr. Nabeel Ahmed, Pharmacist.	Mr. Mohsin Ali Altaf, (Pharm-D) CNIC No.81102-8577102-9

Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person as mentioned below :-

Previous Quality Control Incharge	New Approved Quality Control Incharge
Mr. Nabeel Ahmed, Pharmacist.	Mr. Mohsin Ali Altaf, (Pharm-D) CNIC No.81102-8577102-9

Case No.02.

It is submitted that the case for grant of renewal of establishment License of M/s General Pharma, Farm Road, 03-KM, GT Road, Manhes (Kotli Wagha), Kamoke to manufacture medical devices was approved by the MDB in its 30th meeting held 23-02-2021. After that the firm has applied for approval of change of their Production Incharge as per detail given below:-

Existing Production Incharge	Proposed Production Incharge
Mr. Muhammad Ali Afaq (M.Sc. Chemistry)	Mr. Nishat Anjum (Pharm-B)

Decision: The Board acceded to the request of the firm /company and approved the change of their Production Incharge as mentioned below :-

Previous Production Incharge	New Approved Production Incharge
Mr. Muhammad Ali Afaq (M.Sc. Chemistry)	Mr. Nishat Anjum (Pharm-B)

Case No.03.

M/s Unisa (Pvt) Limited, Main G.T., Adamzai, Akora Khattak, District Nowshera, KPK has requested for approval of additional section to manufacture medical devices (IV Cannula)

Decision: The Board approved the additional section of M/s Unisa (Pvt) Limited, Main G.T., Adamzai, Akora Khattak, District Nowshera, KPK for manufacturing of IV Cannula through assembling.

Item No.IV. POST REGISTRATION VARIATIONS (AD-IV).

Case No.01.

M/s Schazoo SPL Consumer Healthcare, 71-B/C2, Gulberg-III, Lahore has requested for approval of change of legal manufacturer of their already registered medical devices for import as per detail given below. They have further stated that product name and catalogue will remain same:-

S.No.	Product Name	Regn. No.	Existing Name and Address of Manufacturer	Proposed Name and Address of Manufacturer
1.	Hyamira Basic (Reticulated Hyaluronic Acid: 20mg/ml.	MDIR-0000899	M/s Apharm S.r.l, Roma 26-28041, Arona (NO) Italy.	M/s Nyuma Pharma S.r.l, Via San Carlo, 56-28041 Arona (NO) Italy.

2.	Hyamira Forte (Reticulated Hyaluronic Acid: 25mg/ml.	MDIR-0000900	-do-	-do-
3.	Hyamira Soft (Reticulated Hyaluronic Acid: 15mg/ml.	MDIR-0000901	-do-	-do-
4.	Hyamira (Cross- linked Hyaluronic Acid Sodium Salt in prefilled syringe) 1.6% 16mg/ml and 32mg/2ml 2.0% - 20mg/1ml and 40mg/2ml.	MDIR-0000902	-do-	-do-

Decision: The Board approved the request of M/s Schazoo SPL Consumer Healthcare, 71-B/C2, Gulberg-III, Lahore for cancellation of their already above mentioned registered products and approved fresh registration of the above mentioned products with the new manufacturer name and address, namely M/s Nyuma Pharma S.r.l, Via San Carlo, 56-28041 Arona (NO) Italy.

Case No.02.

It is submitted that M/s Islam & Sons, Near Ghee Mills Dargai, Malakand, PKP has requested for extension in shelf life of their already following registered medical devices import: -

Regn. No.	Name of Medical Device	Name of Manufacturer	Approved Shelf Life	Demanded Shelf Life
MDIR-0001893	RTMED Polyglycolic Acid Suture System	Manufacturer: M/s Shandong Haidike zMedical Products Co., Ltd, 88 Meters West of Tainfu Road, Dongcheng Office, Shan County Heze City Shandong Province, China.	03 Year	05 Years
MDIR-0001894	RTMED Silk Non- Absorbable Sutures	-do-	03 Year	05 Years
MDIR-0001895	RTMED Polypropylene Sutures with needle (non absorbable)	-do-	03 Year	05 Years

Decision: The MDB discussed the case and decided to approve the increase in shelf life from 3 years to 5 years of above mentioned products.

Item No.V. CANCELLATION OF SOLE AGENCY AGREEMENT

Decision: The MDB did not agree to the request of the firm for granting extension in time line for one month for filing of proper reply of products namely DORA Disposable A.V. Fistula Needle Sets (Regn. No. MDIR-0000599), DORA Tubing Sets for Hemodialysis (Regn.No. MDIR-0000600) and DORA Hollow Fiber Dialyzer (Regn.No.MDIR-0000601 of M/s Dora Enterprises, however, decided to call the firm to avail the opportunity of personal hearing under the MD Rules, 2017.

Item No.IX. REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s Medicamp, International , Office No 1, First Floor, Raja Naseer Plaza, Mohalla Raja Yousaf, New Abadi Morgah, Rawalpindi (ELI-00200)	Manufacturer: M/s. DELTA MED S.p.A Via Guido Rossa, 20, 46019 Viadana (MN), Italy FSC Italy issued on 17-6-2019	Delta Self Safe 1 (Single entry safety IV catheter with wings) Codes as per FSC Italy dated 17-06-2019 Class B Shelf life: 5 years	Device for peripheral endovenous administration . Sterile, single use	Approved. Firm shall submit valid ISO13485 and MRP .
2.	-do-	Manufacturer: M/s. DELTA MED S.p.A Via Guido Rossa, 20, 46019 Viadana (MN), Italy FSC Italy issued on 17-6-2019	Delta Ven 1 (IV single entry catheter without injection valve) Codes as per FSC Italy dated 17-06-2019 Class B Shelf life: 5 years	Device for peripheral endovenous administration .Sterile, single use	Deferred for clarification from M/s Intra Health, Karachi as the product is already registered with the firm. Firm shall submit valid

					ISO13485 and MRP .
3.	-do-	<p>Manufacturer:</p> <p>M/s. DELTA MED S.p.A Via Guido Rossa, 20, 46019 Viadana (MN), Italy</p> <p>FSC Italy issued on 17-6-2019</p>	<p>Delta Ven 2 (IV dual entry catheter with injection valve)</p> <p>Codes as per FSC Italy dated 17-06-2019</p> <p>Class B</p> <p>Shelf life: 5 years</p>	<p>Device for peripheral endovenous administration .Sterile, single use</p>	<p>Deferred for clarification from M/s Intra Health, Karachi as the product is already registered with the firm.</p> <p>Firm shall submit valid ISO13485 and MRP .</p>
4.	-do-	<p>Manufacturer:</p> <p>M/s. DELTA MED S.p.A Via Guido Rossa, 20, 46019 Viadana (MN), Italy</p> <p>FSC Italy issued on 17-6-2019</p>	<p>Delta Self Safe T</p> <p>(Single entry safety IV catheter without wings)</p> <p>Codes as per FSC Italy dated 17-06-2019</p> <p>Class B</p> <p>Shelf life: 5 years</p>	<p>Device for peripheral endovenous administration . Sterile, single use</p>	<p>Approved.</p> <p>Firm shall submit valid ISO13485 and MRP.</p>
5.	-do-	<p>Manufacturer:</p> <p>M/s. DELTA MED S.p.A Via Guido Rossa, 20, 46019 Viadana (MN), Italy</p> <p>FSC Italy issued on 17-6-2019</p>	<p>Delta Self Safe 2</p> <p>(Dual entry safety IV catheter with wings)</p> <p>Codes as per FSC Italy dated 17-06-2019</p> <p>Class B</p> <p>Shelf life: 5 years</p>	<p>Device for peripheral endovenous administration .Sterile, single use</p>	<p>Approved.</p> <p>Firm shall submit valid ISO13485 and MRP.</p>
6.	-do-	<p>Manufacturer MEDpro Medical B.V. Vendelier 45 E, 3905 PC Veenendaal, The Netherlands</p> <p>FSC Netherlands valid till 26.05.2024</p>	<p>MEDpro Double J Stent-Both end single loop (DJSBES) (Ureteral stent)</p> <p>Sizes: 30 Fr, 35 Fr, 38 Fr, 40 Fr, 45 Fr, 47 Fr, 48 Fr, 50 Fr, 55 Fr, 60 Fr, 70 Fr, 80 Fr</p> <p>Class B</p> <p>Shelf Life: 3 years</p>	<p>Indicated for use in urology procedures to ensure the patency of ureter. Sterile, single use</p>	<p>Approved.</p> <p>Firm shall submit original, valid, notarized Letter of Authorization having updated address of importer (alongwith</p>

					other particulars), valid ISO13485and MRP
7.	-do-	<p>Manufacturer MEDpro Medical B.V. Vendelier 45 E, 3905 PC Veenendaal, The Netherlands</p> <p>FSC Netherlands valid till 26.05.2024</p>	<p>MEDpro PCN Catheter Set</p> <p>Sizes: 8 Fr, 10 Fr, 12 Fr, 14 Fr</p> <p>Class B</p> <p>Shelf Life: 3 years</p>	<p>Used in urology procedures for percutaneous placement of a pigtail catheter in the renal pelvis for nephrostomy drainage. Sterile, single use</p>	<p>Approved.</p> <p>Firm shall submit original, valid, notarized Letter of Authorization having updated address of importer (alongwith other particulars), valid ISO13485and MRP</p>
8.	-do-	<p>Manufacturer MEDpro Medical B.V. Vendelier 45 E, 3905 PC Veenendaal, The Netherlands</p> <p>FSC Netherlands valid till 26.05.2024</p>	<p>MEDpro Guide Wire</p> <p>Sizes: 0.018 Fr, 0.025 Fr, 0.028 Fr, 0.032 Fr, 0.035 Fr, 0.038 Fr</p> <p>Class B</p> <p>Shelf Life: 3 years</p>	<p>Used in urology procedures to gain ureteral access, to establish a tract, and to assist in the placement, replacement and exchange of medical devices during urological procedures. Not intended for PTCA use. Sterile, single use</p>	<p>Approved.</p> <p>Firm shall submit original, valid, notarized Letter of Authorization having updated address of importer (alongwith other particulars), valid ISO13485and MRP</p>
9.	-do-	<p>Manufacturer MEDpro Medical B.V. Vendelier 45 E, 3905 PC Veenendaal, The Netherlands</p> <p>FSC Netherlands valid till 26.05.2024</p>	<p>MEDpro PCN Catheter</p> <p>Sizes: 6Fr, 7Fr, 8Fr, 9Fr, 10Fr, 12Fr, 14Fr</p> <p>Class B</p>	<p>Used in urology procedures for percutaneous placement of a pigtail catheter in the renal pelvis for nephrostomy</p>	<p>Approved.</p> <p>Firm shall submit original, valid, notarized Letter of Authorization</p>

			Shelf Life: 3 years	drainage. Sterile, single use	having updated address of importer (alongwith other particulars), valid ISO13485and MRP
10.	-do-	Manufacturer MEDpro Medical B.V. Vendelier 45 E, 3905 PC Veenendaal, The Netherlands FSC Netherlands valid till 26.05.2024	MEDpro Amplatz Sheath Sizes: 18 Fr, 20 Fr, 22 Fr, 24 Fr, 26 Fr, 28 Fr, 30 Fr, 32 Fr, 34 Fr Class B Shelf Life: 3 years	Used in urology procedures during renal dilatation to provide a traumatic working track after removal of dilator. Provides high radiopacity specification for easy X-ray verification of position. Sterile, single use	Approved. Firm shall submit original, valid, notarized Letter of Authorization having updated address of importer (alongwith other particulars), valid ISO13485and MRP
11.	-do-	Manufacturer MEDpro Medical B.V. Vendelier 45 E, 3905 PC Veenendaal, The Netherlands FSC Netherlands valid till 26.05.2024	MEDproUreteral Catheter Sizes: 3 Fr, 4 Fr, 5 Fr, 6 Fr, 7 Fr Class B Shelf Life: 3 years	Used in urology procedures for drainage and navigation of a tortuous ureter. Sterile, single use	Approved. Firm shall submit original, valid, notarized Letter of Authorization having updated address of importer (alongwith other particulars), valid ISO13485and MRP .
12.	-do-	Manufacturer MEDpro Medical B.V. Vendelier 45 E, 3905	MEDproSuprapubic Catheter Sizes:	Used in urology procedures to provide	Approved. Firm shall submit original,

		PC Veenendaal, The Netherlands FSC Netherlands valid till 26.05.2024	10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr Class B Shelf Life: 3 years	bladder drainage by percutaneous placement of a Malecot catheter. Sterile, single use	valid, notarized Letter of Authorization having updated address of importer (alongwith other particulars), valid ISO13485 and MRP
13.	M/s. Pharma Consultant Pakistan (Pvt) Ltd Suit # 207, 207 A Khan Tower, DHA Square Walton Road Lahore (ELI-00176)	Manufacturer: M/s. LivaNova Deutschland GmbH, Lindberghstr. 25, 80939 Munchen Germany FSC Germany issue Date 26 th November, 2018	STOCKERT S5 (Heart-Lung Machine System) Code:- 45-95-02 Class C Shelf Life: N/A Fee submitted: Rs. 50,000/-	Used to perform, control and monitor extracorporeal blood circulation during an operation.	Approved.
14.	-do-	Manufacturer: M/s. LivaNova Deutschland GmbH, Lindberghstr. 25, 80939 Munchen Germany FSC Germany issue Date 26 th November, 2018	LivaNova Heater-Cooler System 3T Class: C Codes: 16-02-80 Service life: 10 years	The heater-cooler is used with a Stöckert/Sorin Heart-Lung Machine (S3/SC/S5/C5) for the controlled heating/cooling of 3 water circuits during extracorporeal perfusion.	Approved.
15.	-do-	Manufacturer: M/s. LivaNova	LivaNova XTRA Autotransfusion	Indicated for use for	Approved.

		<p>Deutschland GmbH, Lindberghstr. 25, 80939 Munchen Germany</p> <p>FSC Germany issue Date 26th November,2018</p>	<p>Cell Separator</p> <p>Class: C</p> <p>Code: 75220</p> <p>Service Life: 7 years</p>	<p>intraoperative recovery of blood, washing of blood collected in the postoperative period and preoperative sequestration .</p>	
16.	-do-	<p>Manufacturer: M/s. LivaNova Deutschland GmbH, Lindberghstr. 25, 80939 Munchen Germany</p> <p>FSC Germany issue Date 26th November,2018</p>	<p>XVAC (Vacuum Module)</p> <p>Class: B</p> <p>Codes: 75306, 75307</p> <p>Service Life: 7 years</p> <p>Fee submitted: Rs. 25,000/-</p>	<p>A vacuum pump for auto- transfusion applications. Indicated for use for intraoperative and postoperative recovery of blood</p>	Approved.
17.	M/s Meditec Instruments Co., Suit No. 202, Tahir Plaza, A-20, KCSHU, Near Duty Free Shop, Karachi (ELI-00233)	<p>Manufacturer: Guangzhou Wondfo Biotech Co., Ltd. No. 8 Lizhishan Road, Science city, Luogang District, 510663, Guangzhou, China FSC China valid till 06-12-2020</p> <p>FSC Belgium issued on 16-03-2020</p>	<p>Finicare™ CRP Rapid Quantitative Test (Kit)</p> <p>Class: C</p> <p>Code: W201</p> <p>Shelf Life: 24 months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>A fluorescence immunoassay used along with Finicare™ FIA system for quantitative determination of C-reactive protein (CRP) in human whole blood, serum or plasma. This test is used as an aid to predict future cardiovascular diseases as well as to see infection and inflammation</p>	Approved

18.	M/s Cabbot Surgicals, CB-6060 Rose Lane 3-A New Lalazar, Rawalpindi (ELI-00415)	Manufacturer: M/s Zhejiang Nurotron Biotechnology Co., Ltd No.17, Longtan Road, Yuhang District, Hangzhou, China FSC China valid till 16-12-2021	Nurotron Cochlear Implant Class D Model: CS-10A Shelf life: 2 years Fee submitted: Rs. 50,000/-	Active implantable medical device which provides electric stimulation to the residual auditory nerve on the cochlea so as to enable the brain of a severe-to-profound sensorineural deafened patient aged 12 months and above to sense the sound. Sterile	Approved. The firm shall provide notarized CE certificates.
19.	M/s Surgi World Office No. 303, Muhammadi a Plaza, College Road, Rawalpindi ELI-00212	Legal Manufacturer: C.R. BARD Inc. 8195 Industrial Boulevard, Covington, Georgia, USA 30014 Manufacturing Site: C.R. BARD, Inc. 289 Bay Road, Queensbury, New York, USA 12804 FSC US FDA valid till 13-02-2021	Bard Balloon Bipolar Temporary Pacing Electrode (Temporary pacing electrode catheter) Code: 006173P, 006172P Class: D Shelf Life: 2 years Rs.50,000/-	Designed to transmit an external signal from an external pulse generator to the heart or from the heart to a monitoring device. Sterile, single use	Approved. The firm shall provide valid Letter of Authorization , Full QA, ISO 13485, FSC and MRP .
20.	-do-	Legal Manufacturer: C.R. BARD Inc. 8195 Industrial Boulevard, Covington, Georgia, USA 30014 Manufacturing Site: C.R. BARD, Inc. 289 Bay Road, Queensbury, New York, USA 12804 FSC US FDA valid till 13-02-2021	Bard Semi-Floating Temporary Pacing Electrode (Temporary Pacing Electrode Catheter) Codes: 006241P, 006221P, 006242P, 006225P Class D Shelf Life: 5 years Rs.50,000/-	Designed to transmit an external signal from an external pulse generator to the heart or from the heart to a monitoring device. Sterile, single use	Approved. The firm shall provide valid Letter of Authorization , Full QA, ISO 13485, FSC and MRP .

21.	-do-	<p>Legal Manufacturer: C.R. BARD Inc. 8195 Industrial Boulevard, Covington, Georgia, USA 30014</p> <p>Manufacturing Site: BARD, SDN. BHD. LOT 57-C KULIM INDUSTRIAL ESTATE, KULIM, Kedah, Malaysia 09000</p> <p>FSC US FDA valid till 13-02-2021</p>	<p>Bard®Biocath® Suprapubic Catherization Set</p> <p>Code: 561012, 561016</p> <p>Class C</p> <p>Shelf Life: 5 years</p> <p>Rs.50,000/-</p>	<p>Indicated for:</p> <ul style="list-style-type: none"> • Outflow Obstruction • Chronic Retention • Ureteral Trauma • Pre-, intra- and post- operative bladder drainage • Urethral strictures or Fistula <p>Sterile, single use</p>	<p>Approved.</p> <p>The firm shall provide valid Letter of Authorization , Full QA, ISO 13485, FSC and MRP .</p>
22.	-do-	<p><u>Legal manufacturer:</u> M/s Bard Access Systems, Inc 605 North,5600 West, Salt Lake City, Utah (UT) 84116 USA</p> <p><u>Manufacturing Site:</u> M/s Bard Reynosa S.A de C.V. Blvd. Montebello NO 1, Parque Industrial Colonial Reynosa, Tamaulipas Mexico. FSC: US FDA. Valid till: 07.08.2021</p>	<p>Power PICC CATHETER (Peripherally Inserted Central Catheter (PICC) Class- D Shelf Life: 3 years Codes as per FSC</p>	<p>The Power PICC Catheter is indicated for short or long- term peripheral access to the Central Venous System for intravenous therapy, power injection of contrast medium and allows for central venous pressure Monitoring.</p>	<p>Approved.</p> <p>The firm shall provide valid LOA and ISO 13485 .</p>
23.	M/s UDL Distribution (Pvt) Ltd 1-D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073)	<p>Legal Manufacturer: Arrow International, Inc. (subsidiary of Teleflex, Inc.) 2400 Bernville Road Reading, PA 19605 USA</p> <p>Manufacturing sites: 1. Arrow</p>	<p>ARROW Radial Artery Catheterization Set</p> <p>Class D</p> <p>Shelf Life: 5 Years</p> <p>Code: RA-04020</p>	<p>Permits access to the peripheral arterial circulation. Sterile, single use</p>	<p>Approved.</p>

		<p>Internacional de Chihuahua S.A. de C.V. Ave. Washington 3701, interior circuito industrial Alta Tecnologia Edificio 40, Colonia Panamericana Chihuahua, Mexico, 31200.</p> <p>2. Arrow International C.R. A.S. Jamska 2359/47 Zdar Nad Sazavou, Czech Republic 59101</p> <p>(FSC USFDA valid till 04-12-2021)</p>	<p>Fee submitted: Rs. 50,000/-</p>		
24.	<p>M/s Eastern Medical Care (Pvt) Ltd. 7A, Block N, Model Town Extension, Lahore (ELI-00130)</p>	<p>Legal Manufacturer: M/s AMTEC CO., LTD. 1-27-9 Edobori, Nishi-Ku, Osaka, 550-0002, Japan</p> <p>Manufacturing site: M/s THAI AMTEC CO.,LTD. 88/6 Asia Industrial Estate, Suvarnabhumi, Moo 4 T. Khlongsuan Amphur Bangbo, Samutprakarn 10560, Thailand.</p> <p>FSC Thailand valid till 21-07-2022</p> <p>FSC Netherlands valid till 21-08-2021</p>	<p>Citrix-50H (organic-acid based disinfectant)</p> <p>Class C</p> <p>Shelf Life: 24 months</p>	<p>Liquid disinfectant composed of citric acid 33% and malic acid 23% used for heat disinfection of the fluid path of hemodialysis machines.</p>	<p>Approved.</p> <p>The firm shall submit valid Agency agreement .</p>
25.	-do-	<p>Manufacturer: M/s Farmasol Tibbi , Urunler San. Ve Tic. A.S. Organize Sanayi Bolgesi 18. Cad. No: 7 Melikgazi Kayseri Turkey.</p> <p>FSC Turkey valid till</p>	<p>FARMACART B Bag (Powder Sodium Bicarbonate for hemodialysis)</p> <p>Class C</p> <p>Codes: as highlighted on FSC Turkey</p>	<p>Used for obtaining Basic Bicarbonate Hemodialysis Concentrate for extra-corporal bicarbonate hemodialysis</p>	<p>Approved.</p>

		26-07-2023	Shelf Life: 36 months	or bicarbonate hemofiltration. Non-sterile, single use	
26.	-do-	<p>Manufacturer: M/s Farmasol Tibbi , Urunler San. Ve Tic. A.S. Organize Sanayi Bolgesi 18. Cad. No: 7 Melikgazi Kayseri Turkey.</p> <p>FSC Turkey valid till 26-07-2023</p>	<p>DIADEZ M2.5 L2.5 Disinfectant</p> <p>Class C</p> <p>Shelf Life: 2 years</p>	<p>Contains 21% citric acid, 2.5% malic acid and 2.5% lactic acid. It is a Concentrated hemodialysis machine disinfectant and used in Fresenius hemodialysis machines for thermochemical disinfection and decalcification purpose. Non-sterile, single use</p>	Approved.
27.	-do-	<p>Manufacturer: M/s Farmasol Tibbi , Urunler San. Ve Tic. A.S. Organize Sanayi Bolgesi 18. Cad. No: 7 Melikgazi Kayseri Turkey.</p> <p>FSC Turkey valid till 26-07-2023</p>	<p>FARMACART B Cartridge (Sodium Bicarbonate for hemodialysis)</p> <p>Class C</p> <p>Codes: as highlighted on FSC Turkey</p> <p>Shelf Life: 36 months</p> <p>Fee submitted: Rs. 25,000/-</p>	<p>Used for obtaining Basic Bicarbonate Hemodialysis Concentrate for extra-corporal bicarbonate hemodialysis or bicarbonate hemofiltration. Non-sterile, single use</p>	Approved.
28.	M/s Hope Pharma Office No.1-B, Guldasht Town, Zarar Shaheed Road, Lahore	<p>Manufacturer: Medas, Inc 12550 Biscayne Boulevard 4th Floor, Suite 405 North Miami, FL 33181 USA</p> <p>FSC USFDA valid till 24-03-2023</p>	<p>MEDADV central venous catheter kit (triple lumen)</p> <p>Codes: As highlighted on US FDA FSC No. 87841-5-2021 dated 25-3-2021</p> <p>Class D</p> <p>Shelf life: 3 years</p>	<p>Used to deliver fluids and medications through temporary access to large blood vessels which require rapid supply to the central vascular system. Sterile, single use</p>	Approved.

	ELI-00178				
29.	-do-	<p>Manufacturer: Medas, Inc 12550 Biscayne Boulevard 4th Floor, Suite 405 North Miami, FL 33181 USA</p> <p>FSC USFDA valid till 24-03-2023</p>	<p>MEDADV hemodialysis catheter kit (Double lumen, short term hemodialysis catheter)</p> <p>Codes: As highlighted on US FDA FSC No. 87841-5-2021 dated 25-3-2021</p> <p>Class B</p> <p>Shelf life: 3 years</p>	<p>Hemodialysis catheter are the sterile, single use range of short- term use polyurethane catheters designed to facilitate infusion or hemodialysis therapy in a critical care environment. Sterile, single use</p>	Approved.
30.	<p>M/s Capra- Med (Pvt) Ltd. First Floor, 81 Broadway Commercial Paragon city, Barki Road, Lahore</p> <p>ELI: 00656</p>	<p>Legal Manufacturer: International Company for Medical Necessities, 3rd Industrial Zone, Block No. 19&67, El-Zarby, Abu-Tig, Assiut, Egypt</p> <p>Manufacturing site: 1. International Company for Medical Necessities, 3rd Industrial Zone, Block No. 19&67, El-Zarby, Abu-Tig, Assiut, Egypt 2. International Company for Medical Necessities, Public Free Zone, Ismailia, Egypt</p> <p>FSC Egypt valid till 26-05-2024 FSC Belgium issued on 04-02-2021</p>	<p>I.CO Hypodermic Syringe 1 ml Insulin</p> <p>Class B</p> <p>Shelf Life: 5 years</p>	<p>Sterile, single- use insulin syringe</p>	Approved.
31.	-do-	<p>Legal Manufacturer: International</p>	<p>I.CO Hypodermic Syringe 20ml, 50ml</p>	<p>Syringe used to inject fluid into, or</p>	Approved.

		<p>Company for Medical Necessities, 3rd Industrial Zone, Block No. 19&67, El-Zarby, Abu-Tig, Assiut, Egypt</p> <p>Manufacturing site: 1. International Company for Medical Necessities, 3rd Industrial Zone, Block No. 19&67, El-Zarby, Abu-Tig, Assiut, Egypt 2. International Company for Medical Necessities, Public Free Zone, Ismailia, Egypt</p> <p>FSC Egypt valid till 26-05-2024 FSC Belgium issued on 04-02-2021</p>	<p>Class B</p> <p>Shelf Life: 5 years</p>	<p>withdraw fluid from the body Sterile, single-use</p>	
32.	<p>M/s Zam Zam Corporation Suit # 205-206, 2nd floor, 6-CL-10, Beaumont Plaza, Karachi</p> <p>ELI-00412</p>	<p>Manufacturer: GMD Group Medikal San. Ve TIC. A.S IKITELLI OSB MAH. ISDOK SOSYAL TESIS 2 SK. B BLOK 1 B 7 BASAKSEHIR/ISTA NBUL Turkey</p> <p>FSC Turkey valid till 3-10-2022</p>	<p>DAMACRYL 910 Polyglactin (PGLA) suture</p> <p>Codes as per FSC Turkey dated 4-10-2019</p> <p>Class D</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Sterile, single-use, synthetic, absorbable, PGLA surgical suture indicated for use in general soft tissue approximation where mid-term wound support (2-3 weeks) is require</p>	<p>Approved. Firm shall submit Notarized letter of authorization and ISO13485 .</p>
33.	-do-	<p>Manufacturer: GMD Group Medikal San. Ve TIC. A.S IKITELLI OSB MAH. ISDOK SOSYAL TESIS 2 SK. B BLOK 1 B 7 BASAKSEHIR/ISTA NBUL, TURKEY</p> <p>FSC Turkey valid till 3-10-2022</p>	<p>DAMAESTER suture</p> <p>Codes as per FSC Turkey dated 4-10-2019</p> <p>Class D</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Sterile, single-use, synthetic, non-absorbable, polyester, multifilament surgical suture indicated for use in soft tissue approximation and/or ligation,</p>	<p>Approved. Firm shall submit Notarized letter of authorization and ISO13485 .</p>

				including ophthalmic procedures and cardiovascular surgery.	
34.	-do-	<p>Manufacturer: GMD Group Medikal San. Ve TIC. A.S IKITELLI OSB MAH. ISDOK SOSYAL TESIS 2 SK. B BLOK 1 B 7 BASAKSEHIR/ISTA NBUL, TURKEY</p> <p>FSC Turkey valid till 3-10-2022</p>	<p>DAMADIAOXANO NE polydioxanone suture</p> <p>Codes as per FSC Turkey dated 4-10- 2019</p> <p>Class D</p> <p>Shelf life: 3 years</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Sterile, single- use, synthetic, absorbable, polydioxanone monofilament surgical suture indicated for use in all types of soft tissue approximation including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic procedures.</p>	<p>Approved. Firm shall submit Notarized letter of authorization and ISO13485 .</p>
35.	-do-	<p>Manufacturer: GMD Group Medikal San. Ve TIC. A.S IKITELLI OSB MAH. ISDOK SOSYAL TESIS 2 SK. B BLOK 1 B 7 BASAKSEHIR/ISTA NBUL, TURKEY</p> <p>FSC Turkey valid till 3-10-2022</p>	<p>DAMACAPRONE poliglecaprone suture</p> <p>Codes as per FSC Turkey dated 4-10- 2019</p> <p>Class D</p> <p>Shelf life: 2 years</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Sterile, single- use, synthetic, absorbable, poliglecaprone monofilament surgical suture indicated for use in general soft tissue approximation and/or ligation</p>	<p>Approved. Firm shall submit Notarized letter of authorization and ISO13485 .</p>
36.	-do-	<p>Manufacturer: GMD Group Medikal San. Ve TIC. A.S IKITELLI OSB MAH. ISDOK SOSYAL TESIS 2 SK. B BLOK 1 B 7 BASAKSEHIR/ISTA NBUL, TURKEY</p> <p>FSC Turkey valid till 3-10-2022</p>	<p>DAMACRYL RAPID polyglactin- 910 suture</p> <p>Codes as per FSC Turkey dated 4-10- 2019</p> <p>Class D</p> <p>Shelf life: 3 years</p>	<p>Sterile, single- use, synthetic fast absorbable, PGLA surgical suture indicated only for use in soft tissue approximation where only short term</p>	<p>Approved. Firm shall submit Notarized letter of authorization and ISO13485 .</p>

			Fee submitted: Rs. 50,000/-	wound support is required including ophthalmic surgery.	
37.	-do-	<p>Manufacturer: GMD Group Medikal San. Ve TIC. A.S IKITELLI OSB MAH. ISDOK SOSYAL TESIS 2 SK. B BLOK 1 B 7 BASAKSEHIR/ISTA NBUL, TURKEY</p> <p>FSC Turkey valid till 3-10-2022</p>	<p>DAMASILK suture</p> <p>Codes as per FSC Turkey dated 4-10-2019</p> <p>Class C</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Sterile, single-use, synthetic, non-absorbable, multifilament surgical suture made of silk indicated for use in general soft tissue approximation and ligation and used in variety of surgical sutures</p>	<p>Approved. Firm shall submit Notarized letter of authorization and ISO13485 .</p>
38.	-do-	<p>Manufacturer: GMD Group Medikal San. Ve TIC. A.S IKITELLI OSB MAH. ISDOK SOSYAL TESIS 2 SK. B BLOK 1 B 7 BASAKSEHIR/ISTA NBUL, TURKEY</p> <p>FSC Turkey valid till 3-10-2022</p>	<p>DAMACRYL polyglycolic acid suture</p> <p>Codes & Sizes as per FSC</p> <p>Class D</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Sterile, single-use, synthetic absorbable, PGA surgical suture indicated only for use in soft tissue approximation where wound support is required including ophthalmic surgery.</p>	<p>Approved. Firm shall submit Notarized letter of authorization and ISO13485 .</p>
39.	M/s Global Marketing Services, 111, Hali Road Westridge1 , Rawalpindi ELI: 00109	<p>Manufacturer: Biotronik SE & Co.KG Woermannkehre 1, 12359 Berlin, Germany</p> <p>FSC Germany issued on 10-08-2020</p>	<p>Inlexa 3 VR-T (Implantable cardioverter defibrillator-MR Conditional)</p> <p>Code: 404703 404704</p> <p>Class: D</p> <p>Shelf Life: 19 months</p> <p>Fee submitted: Rs.</p>	<p>Single chamber implantable cardioverter defibrillator, MR conditional, sterile, single-use</p>	<p>Approved.</p>

			50,000/-		
40.	-do-	<p>Manufacturer: Biotronik SE & Co.KG Woermannkehre 1, 12359 Berlin, Germany</p> <p>FSC Germany issued on 10-08- 2020</p>	<p>Inlexa 3 HF-T (Implantable cardioverter defibrillator-MR Conditional)</p> <p>Code: 404699 404700</p> <p>Class: D</p> <p>Shelf Life: 19 months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Triple chamber implantable cardioverter defibrillator, MR conditional, sterile, single-use</p>	<p>Approved. Firm shall submit MRP</p>
41.	-do-	<p>Manufacturer: Biotronik SE & Co.KG Woermannkehre 1, 12359 Berlin, Germany</p> <p>FSC Germany issued on 10-08- 2020</p>	<p>Inlexa 3 DR-T (Implantable cardioverter defibrillator-MR Conditional)</p> <p>Code: 404701, 404702</p> <p>Class: D</p> <p>Shelf Life: 19 months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Dual chamber implantable cardioverter defibrillator, MR conditional, sterile, single-use</p>	<p>Approved.</p>
42.	-do-	<p><u>Legal</u> <u>Manufacturer:</u> BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile - France <u>Manufacturing Site:</u> BioMérieux SA 3 route de Port Michaud 38390 La Balme les grottes – France FSC France Date of issue:13th Dec.2017</p>	<p>API ID Strip Range Class: B Shelf life: Codes: 10100, 10300, 10500, 20050, 20100, 20120, 20150, 20210, 20230, 20300, 20500, 20600, 20900, 40011, 50110, 50120, 50300, 50410, 50430, 55561, 70100, 70380, 70402, 70422, 70442, 70491, 70492, 70493, 70494, 70510, 70520, 70530, 70542, 70700, 70900, 20800</p>	<p>API identification products are test kits for identification of Gram- positive and Gram- negative bacteria and yeast. The system offers a large and robust database accessible through the</p>	<p>Approved.</p>

				Internet-based APIWEB™ service	
43.	-do-	<p>Legal Manufacturer: BioMérieux, Inc.100 Rodolphe Street Durham, NC 27712 - USA Manufacturing Site: bioMérieux, Inc., St. Louis 595 Anglum Rd Hazelwood, MO63042 – USA FSC: France Date of Issue: 25th July,2018</p>	<p>VITEK 2 ID Cards</p> <p>VITEK 2 GN 21341 12 Months</p> <p>VITEK 2 GP 21342 18 Months</p> <p>VITEK 2 YST 21343 18 Months</p> <p>VITEK 2 ANC 21347 18 Months</p> <p>Class- B</p>	<p>The VITEK® 2 ID Cards are intended for use with VITEK 2 SYSTEM for automated identification of most clinically significant aerobic, anaerobic, fermenting, non-fermenting, gram positive and negative bacteria and yeast.</p>	Approved.
44.	-do-	<p>Legal Manufacturer: BioMérieux SA376 chemin de l’Orme 69280 Marcy l’Etoile - France Manufacturing Site: BioMérieux SA376 chemin de l’Orme 69280 Marcy l’Etoile – France</p> <p>FSC: France</p> <p>Date of issue: 13.12.2017</p>	<p>VIDAS CA 125 II (OC 125 antigenic detector) (Ref. 30426)</p> <p>Class: C</p> <p>Shelf life: 12th Months.</p>	<p>VIDAS CA 125 II is an automated quantitative test for use on the VIDAS family instruments, for the measurement of OC 125 antigenic determinants in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).</p>	Approved.
45.	-do-	<p>Legal Manufacturer: BioMérieux SA 376 chemin de l’Orme</p>	<p>VIDAS CA 15-3 (CA 15-3 levels detector) Class-C</p>	<p>VIDAS CA 15-3 is an automated quantitative</p>	Approved.

		69280 Marcy l'Etoile - France <u>Manufacturing Site:</u> BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile – France FSC: France Date of issue: 13.12.2017	Shelf life: 12 months Codes as per FSC	test for use on the VIDAS family instruments for the quantitative measurement of CA 15-3 levels in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).	
46.	-do-	<u>Legal Manufacturer:</u> BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile - France <u>Manufacturing Site:</u> BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile – France FSC: France Date of issue: 13.12.2017	VIDAS CA 19-9 (1116-NS-19-9 reactive antigenic determinants detector Class: C Shelf life: 12months Codes as per FSC	VIDAS CA 19-9 is an automated quantitative test for use on the VIDAS family instruments for the measurement of 1116- NS-19-9 reactive antigenic determinants in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay).	Approved.
47.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th	Manufacturer: Ethicon Inc. Route 22 West, P.O. Box 151, Somerville, New Jersey USA, 08876.	ENDOLOOP ligature made with coated VICRYL™ (Polyglactin 910) suture	Sterile, single use device indicated for use in general soft tissue approximation	Approved. Firm shall submit valid FSC and ISO13485 .

	Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154)	(FSC US FDA valid till 17-12-2020)	Codes: EJ10G Class D Shelf Life: 60 Months	and/or ligation including use of ophthalmic procedures but not for use in cardiovascular and neurological tissues	
48.	-do-	Legal Manufacturer: Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754 Manufacturing site: Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754 (FSC US FDA valid till 10-04-2020)	PERMA-HAND™ Braided Silk Non- absorbable suture Codes: W936, 685G, W936G, K871H, K833H, W509, W509G, 684G, 1676G, 1677G, 734G, 1679H, 591H, 1925G, 632H, 1984G, W672G, W794G, W576G, K881H, W604G, 1588H (FSC of USFDA does not have codes. The manufacturer has given list of codes (notarized) that are manufactured by them) Class D Shelf Life: 60 Months	Sterile, single use silk indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular , ophthalmic and neurological procedures	Approved. Firm shall submit valid FSC and ISO13485 .
49.	M/s Safeway Systems Pakistan, Flat No. 4, 2 nd Floor, Amna Shopping Centre, Misrial Road, Rawalpindi.	Manufacturer: Bicakcilar Tibbi Cihazlar Sanayi Ve Ticaret. A.S. OSMANGAZI Mah. Gazi Cad, No. 21 34522, Esenyurt, Istanbul, Turkey FSC Turkey valid till 19-05-2023	Bicakcilar Cardioplegia set Codes: 32505821, 32506111, 32508511, 32505811, 32509311 Class D Shelf Life: 5 years	Sterile, disposable medical device used to deliver cardioplegia solution during open heart surgery. Single -use	Approved. Firm shall submit Original and Notarized Letter of Authorization .

	(ELI-00308)				
50.	-do-	<p>Manufacturer: Bicakcilar Tibbi Cihazlar Sanayi Ve Ticaret. A.S. OSMANGAZI Mah. Gazi Cad, No. 21 34522, Esenyurt, Istanbul, Turkey</p> <p>FSC Turkey valid till 19-05-2023</p>	<p>Bicakcilar Cannulation Tourniquet set with snare</p> <p>Codes: 33005181,33005111, 33005131, 33005161</p> <p>Class B</p> <p>Shelf Life: 5 years</p>	<p>Intended to be used in a surgical procedure where it is desired to limit or restrict flow through cannulation within such vessel. Sterile, single use</p>	<p>Approved. Firm shall submit Original and Notarized Letter of Authorization .</p>
51.	-do-	<p>Manufacturer: Bicakcilar Tibbi Cihazlar Sanayi Ve Ticaret. A.S. OSMANGAZI Mah. Gazi Cad, No. 21 34522, Esenyurt, Istanbul, Turkey</p> <p>FSC Turkey valid till 19-05-2023</p>	<p>Bicakcilar Vessel Cannula with valve</p> <p>Code: 33002211</p> <p>Class D</p> <p>Shelf Life: 5 years</p>	<p>Intended for use in cardiovascular surgical procedures to test the integrity of vein grafts prior to anastomosis to coronary arteries and to facilitate antegrade cardioplegia administration directly down the vein graft following completion of the distal anastomosis. Sterile, single use</p>	<p>Approved. Firm shall submit Original and Notarized Letter of Authorization .</p>
52.	-do-	<p>Manufacturer Sienco, Inc. 5721 Arapahoe Ave, Unit A1-A, Boulder, CO USA 80303</p> <p>FSC US FDA not provided FSC Netherlands valid till 26-05-2025</p>	<p>Sonoclot Coagulation analyzer with SonoView software</p> <p>Model: SC1</p> <p>Class B</p> <p>Shelf Life: N/A</p>	<p>Analyzer for measurement of activated clotting time (ACT) and the Clot Rate (CR)</p>	<p>Approved.</p>

53.	-do-	<p>Legal Manufacture: BRAILE BIOMEDICA BRAZI, AV Pres. Juscelino K. de Oliveira, 1505-Tarrafa I, saojose do Rio Preto-SP, 15091-450, Brazil</p> <p>FSC: Brazil issuance: 25.01.2018</p>	<p>BRAILE PATCH DE PERICARDIO BOVINO (Bovine Pericardium Patch)</p> <p>Class D</p> <p>Shelf Life: 4 years</p>	<p>Cardiovascular Surgery: closure of intercavitary defects, expansion of the outflow tract of the right ventricle, widening of the aortic ring in valvar exchanges, treatment of aorta and left ventricle aneurysms, atrial and ventricular reconstructions, mustard surgeries, peripheral arterioplasties.</p>	<p>Deferred for provision of FSC of any reference country or CE mark documents.</p>
54.	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite No. 216, Khayaban- e-Jami, Block No.9, Clifton, Karachi (ELI-00006)	<p>Legal Manufacturer: M/s B.Braun Melsungen AG Carl- Braun-Straße 1 34212 Melsungen, Germany</p> <p>Manufacturing Site: M/s B. Braun Medical Industries Sdn. Bhd. Bayan Lepas Free Industrial Zone, 11900 Penang, Malaysia</p> <p>FSC Germany issued on 27-08-2019</p>	<p>Introcan Safety®-W I.V. cannulae</p> <p>Codes as per FSC Germany dated 27- 08-2019</p> <p>Class: B</p> <p>Shelf life: 5 years</p>	<p>An I.V. cannula with wings and without injection port that has safety shield which covers the needle after use to reduce the risk of accidental needle sticks. Sterile, single- use</p>	<p>Approved.</p>
55.	-do-	<p>Legal Manufacturer: M/s B.Braun Melsungen AG Carl- Braun-Straße 1 34212 Melsungen, Germany</p>	<p>Introcan®-W I.V. cannulae</p> <p>Class: B</p> <p>Shelf life: 5 years</p> <p>Codes as per FSC</p>	<p>Indwelling I.V. cannula with wings. Sterile, single- use</p>	<p>Approved.</p>

		<p>Manufacturing Site: M/s B. Braun Medical Industries Sdn. Bhd. Bayan Lepas Free Industrial Zone, 11900 Penang, Malaysia</p> <p>FSC Germany issued on 27-08-2019</p>	Germany dated 27-08-2019		
56.	<p>M/s Ferozsons Laboratories Ltd P.O Ferozsons, Amangarh, Nowshera (KPP) Pakistan ELI-00120</p>	<p>Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA.</p> <p>Manufacturing sites: Boston Scientific Corporation 2546 First Street, Propark, El Coyol, Alajuela, COSTA RICA 20904. FSC: FDA. US. Food & Drug Valid till: 7th Feb. 2021</p>	<p>Zebra™ Guidewire (Gastro-urological guidewire)</p> <p>Class: B</p> <p>Shelf Life: 36th Months</p> <p>Codes: M0066701151 08714729191278 0.038” X 150cm/ Angle Tip M0066701131 08714729191261 0.035” X 150cm/ Angle Tip M0066701121 08714729191254 0.035” X 150cm/ Straight Tip M0066701141 08714729155232 0.038” X 150cm/ Straight Tip M0066701081 08714729191216 0.025” X 150cm/ Straight Tip M0066701091 08714729191223 0.025” X 150cm/ Angle Tip M0066701101 08714729191230 0.032” X 150cm/ Straight Tip M0066701111 08714729191247 0.032” X 150cm/ Angle Tip</p>	<p>The Zebra Urological Guidewires are intended to facilitate the placement of endourological instruments during diagnostic or interventional procedures. These guide wires are not intended for coronary artery, vascular or neurological use.</p>	<p>Approved. The firm shall provide valid FSC and ISO:13485.</p>

57.	-do-	<p>Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA.</p> <p>Manufacturing sites: Boston Scientific Corporation 2546 First Street, Propark, El Coyol, Alajuela, COSTA RICA 20904. FSC: FDA. US. Food & Drug Valid till: 7th Feb. 2021</p>	<p>Sensor™ Nitinol Wire with Hydrophilic Tip (GastroUrological guidewire, single-use)</p> <p>CLASS: B</p> <p>Shelf Life 36th Months Codes: M0066703121 08714729257349 0.038” X 150cm/Straight Tip Dual Flex M0066703011 08714729302612 0.035” X 150cm/Angle Tip Dual Flex M0066703021 08714729302629 0.038” X 150cm/Angle Tip Dual Flex M0066703051 08714729302650 0.035” X 150cm/ Straight Tip M0066703061 08714729302667 0.035” X 150cm/Angle Tip M0066703081 08714729302681 0.035” X 150cm/ Straight Tip Dual Flex M0066703101 08714729257325 0.038” X 150cm/Angle Tip M0066703091 08714729257318 0.038” X 150cm/ Straight Tip</p>	<p>Sensor Guidewires are intended to facilitate the placement of endourological instruments during diagnostic or interventional procedures. These Guidewires are not intended for coronary artery, vascular or neurological use.</p>	<p>Approved. The firm shall provide valid FSC and ISO:13485 .</p>
58.	Batla	Legal	New Golden	Disposable	Approved.

	Impex, Sh. 40, Namco Centre, Cambell Street, Karachi (ELI-00170)	Manufacturer: M/s Zibo Eastmed Healthcare Products Co. Ltd., No.118, Huaguang Road, Zhangdian District Zibo 255000 Shandong, China FSC China issuance (03-09-2019) valid for 5 years FSC MHRA issuance 27-09-2019	Disposable Syringe with Needle Class-B Shelf life: 5 years Codes & Sizes as per FSC 1ml, 10ml, 20ml, 30ml, 50ml, 60ml	syringe	
59.	-do-	Legal Manufacturer: M/s Zibo Eastmed Healthcare Products Co. Ltd., No.118, Huaguang Road, Zhangdian District Zibo 255000 Shandong, China FSC China issuance (03-09-2019) valid for 5 years FSC MHRA issuance 27-09-2019	New Golden Disposable Infusion Set Class-B Shelf life: 5 years Codes & Sizes as per FSC DM002, DM003, DM004, DM018, DM019, DM020, DM005	Tubing set used to carry fluids at a slow, controlled rate from a reservoir to a patient	Approved.
60.	-do-	Legal Manufacturer: M/s Zibo Eastmed Healthcare Products Co. Ltd., No.118, Huaguang Road, Zhangdian District Zibo 255000 Shandong, China FSC China issuance (03-09-2019) valid for 5 years FSC MHRA issuance 27-09-2019	New Golden Blood Transfusion Set Class-B Shelf life: 5 years Codes & Sizes as per FSC DMYX-02, DMYX-03, DMYX-04, DMYX-05	It is used for various medical conditions to replace lost components of the blood.	Approved.
61.	-do-	Legal Manufacturer: M/s Zibo Eastmed Healthcare Products Co. Ltd., No.118, Huaguang Road, Zhangdian District	New Golden Disposable Infusion Set with Burette Class-B Shelf life: 5 years Codes & Sizes as per	Tubing set used to carry fluids at a slow, controlled rate from a reservoir to a	Approved.

		Zibo 255000 Shandong, China FSC China issuance (03-09-2019) valid for 5 years FSC MHRA issuance 27-09-2019	FSC 100ml, 120ml, 150ml	patient and containing a burette.	
62.	M/s Melamine Emporium, Office No.814, Star City Mall, Saddar, Karachi (ELI-00414)	Legal Manufacturer: M/s Tianck Medical Co., Ltd., Building C, No.16 Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen 518119, China FSC UK Issuance (26-03-2018)	Tianck Sterile Introducer Set Introducer sheath Class-B Shelf life: 3 years Codes & Sizes as per FSC	it is used for the use through femoral artery or radial artery to establish a percutaneous access pathway which is helpful for endovascular devices.	Approved.
63.	M/s Mars Enterprises, Office No.4, Jason Centre, 2 nd Floor, BC-8, Block No.9, Clifton, Karachi. (ELI-00097)	Legal Manufacturer: Anhui Easyway Medical Supplies Co., Ltd, No. 737 East Jianshe Road, Tianchang City, Anhui Province, China. (FSC China validity 26-06-2020) FSC Germany 12- 12-2019	i care disposable sterile blood transfusion set for single use (with filter) Class B Shelf Life: 5 Years Sizes & Codes as Per FSC	The propose device is plastic, disposable and sterile blood transfusion set, which is intended to be used to administer blood from the container to a patient's vascular system through a needle or catheter inserted into a vein via gravity method.	Approved.
64.	M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061)	Legal Manufacturer: Medin Medical Innovations GmbH Adam-Geisler-Str.1 82140 Olching Deutschland/German y (FSC Germany 13-	Medijet® nCPAP Generator Class B Shelf Life: N/A Medijet® REF 1000	Medijet® 1000 is a single use product for nCPAP therapy/ noninvasive ventilation therapy in	Approved.

		09-2017)		treating neonates and premature infants in intensive care units.	
65.	-do-	Legal Manufacturer: Medin Medical Innovations GmbH Adam-Geisler-Str.1 82140 Olching Deutschland/Germany (FSC Germany 13-09-2017)	Breathing Circuits heated (nCPAP accessories) Class B Shelf Life: 3 Years Circuits heated REF 1207, 1207MKI	This circuit is for nCPAP applications. Use it together with miniflow® /Medijet® generators. It is a non-sterile and disposable circuit for single patient use only.	Approved.
66.	-do-	Legal Manufacturer: Medin Medical Innovations GmbH Adam-Geisler-Str.1 82140 Olching Deutschland/Germany (FSC Germany 13-09-2017)	Medin Nasal Cannula Class B Shelf Life: 3 Years Codes / models: REF 1300 (0), 1301(0.5), 1302(1)	The oxygen Nasal Cannula Loop is a single use oxygen delivery system consisting of a silicone nasal cannula body.	Approved.
67.	-do-	Legal Manufacturer: M/s Fisher & Paykel Healthcare Limited, 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand FSC New Zealand Issuance Date (05-03-2020)	Optiflow Junior 2 Nasal Cannula Class B Shelf Life: 3 years Model: OJR410, OJR412, OJR414, OJR416, OJR418	Nasal cannula is used to deliver nasal high flow therapy in spontaneously breathing patients.	Deferred for provision of Free Sale Certificate of any reference country or CE mark documents.
68.	-do-	Legal Manufacturer: M/s Fisher & Paykel Healthcare Limited, 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand	MR 850 Humidifier (Respiratory Humidifier system) Class-C Service Life: 7 years Model:	Used to warm and humidifying gases delivered to patients requiring mechanical	Deferred for provision of Free Sale Certificate of any reference

		FSC New Zealand Issuance Date (05-03-2020)	MR850AEU	ventilation, positive pressure breathing assistance, or other medical gases.	country or CE mark documents.
69.	-do-	Legal Manufacturer: Fisher & Paykel Healthcare Limited 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand. FSC New Zealand issuance	Fisher & Paykel BCPAP Nasal Prongs Class-B Shelf life: N/A Codes as per FSC	Nasal prong style CPAP masks use silicone prongs that insert directly into the nose to deliver air pressure.	Deferred for provision of Free Sale Certificate of any reference country or CE mark documents.
70.	M/s. Physiomed Pvt Ltd 268/3, Kamal Road, Saddar, Rawalpindi ELI-00199	Legal Manufacturer: Irvine Biomedical INC, a St Jude Medical Company 2375 Morse Ave Irvine CA USA FSC – USA Valid till 27 th November,2020	Inquiry TM Afocus II TM Diagnostic Catheters (Inquiry TM Afocus II TM Diagnostic Catheters. Class- D Shelf Life: 3 years Codes as per FSC	For recording intracardiac signals and cardiac stimulation during diagnostic electrophysiologic studies. Inquiry TM Afocus TM catheters are for use in mapping atrial regions of the heart.	Approved. Firm shall submit valid Letter of Authorization and valid FSC.
71.	-do-	Legal Manufacturer: Irvine Biomedical INC, a St Jude Medical Company 2375 Morse Ave Irvine CA USA FSC – USA Valid till 27 th November,2020	Inquiry TM Streeable Diagnostic Catheters (Electrophysiology Catheter) Class- D Shelf Life: 3 years Codes as per FSC	The Inquiry Diagnostic Catheter is used for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies. The catheters are commonly	Approved. Firm shall submit valid Letter of Authorization and valid FSC.

				placed at the high right atrium, right ventricular apex and HIS bundle.	
72.	M/s Intek Corporation, Office NO, 30, AL Amin Plaza, the Mall, Rawalpindi. ELI-00034	Legal Manufacturer: TERUMO CORPORATION 44-1, 2-Chome, Hatagaya, Shibuya-Ku, Tokyo 151-0072 JAPAN Manufacturing Site TERUMO CORPORATION ASHITAKA FACTORY Address: 150, Maimaigi-Cho, Fujinomiya City, Shizuoka Prefecture 418-0015, Japan FSC: JAPAN Date of issue: 29 th Sep.2017	Radifocus Glidewire Advntage (Glidewire Advantage) Class-B Shelf Life.24 months Codes: RA*CA35185CM RA*CS35265CM RA*FA18181CM RA*FS14301CM RA*CA35265CM RA*FA14181CM RA*FA18301CM RA*FS18181CM RA*CS35185CM RA*FA14301CM RA*FS14181CM RA*FS18301CM	The guidewires Advantage is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures, except for central circulatory system.	Approved. Firm shall submit valid Letter of Authorization and valid ISO:13485.
73.	M/s J.F International , 4th Floor, 10-C, 6th Sunset Commercial Lane Phase 2 Ext, DHA Karachi ELI-00246	Legal Manufacturer: Longfian Scitech Co., Ltd 2F & 3F, East Section, Building 12, power valley pioneer park, No. 369 Huiyang street, 071051, Baoding, hebei Province China. China FSC validity 17-03-2022	LONGFIAN (Oxygen Concentrator) Class B Shelf Life: 20,000 hours Model: JAY-5	Oxygen Concentrator	Rejected as the same product of this manufacturer has already been registered in the name of M/s Nasir Brothers, Karachi.
74.	M/s. Global Health Care, Midway Commercial Plaza No, 20, Back Side of Prism	Legal Manufacturer: Troge Medical Milchstrasse19, 20148 Hamburg Germany. FSC: Germany Date of issue: 17 th	TRO-SPINOJECT (Spinal Needles) Class C Shelf Life: 5 years. Codes/ models:	Tro Spino Ject consists of a thin walled needle and a mandarin made of stainless steel. The	Approved subject to verification of fee.

	Arcade 2, Bharia Town Phase-7 Rawalpindi ELI-00086	Sep.2018	MD0101 (520xx, 521xx, 522xx)	transparent luer lock permits an immediate control during puncture, the high precision Quincke bevel allows comfortable puncture with minimal trauma. Sterile pyrogen free and atoxic. They are provided with protection cap. For use in sub arachnoid injection of local anesthetics for spinal anesthesia before surgery, and in lumber puncture for pain management and diagnosis on the basis of cerebro spinal fluid.	
75.	Ms. Universal Dental (Pvt) Ltd, 17 Mcleod Road Lahore ELI 00071	<u>Legal Manufacturer:</u> Septodont, 58 rue du ponte Creteil 94107 saint-Maur-des, Fosses Cedex, France FSC France. Date of issue 08- 062020	Endomethasone N (Root Canal filling cement) Class D Shelf life 36th months Code: 2613N	Permanent root canal filling and sealing in dental procedures with systematic insertion of Gutta=Percha points.	Approved.
76.	-do-	<u>Legal Manufacturer:</u> Septodont, 58 rue du ponte Creteil 94107 saint-Maur-des,	SEPTOJEC Dental needle Class B Shelf life 5 years Code as per FSC	Sterile, siliconized, two-point needles for dental	Approved.

		Fosses Cedex, France FSC France. Date of issue 08-06-2020		cartridge syringe. These needlers are single-use and non-sterilizable.	
77.	M/s Platinum Corporation, F-10/7/6, Near Arfeen Masjid, Barrage Colony, Sukkur (ELI-00443)	Legal Manufacturer: M/s Yangzhou Medline Industry Co., Ltd., 108, Jinshan Road, Economic Development Zone, Yangzhou China FSC China Valid Till (28-08-2021)	Sterile disposable Syringe with Needle Class-B Shelf Life: 5 years Sizes: (10ml, 20ml)	Disposable syringe	Deferred for provision of FSC of any reference country or CE mark documents.
78.	Medtronic Pakistan (Pvt) Ltd., Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273)	Legal Manufacturer: M/s Medtronic Inc., 8200 Coral Sea Street NE Mounds View, MN 55112, USA. Manufacturer: M/s Medtronic Singapore Operations Pte Ltd., 49 Changi South Avenue 2 Nasaco Tech Centre Singapore, 486056, Singapore. FSC USFDA Valid Till (15-08-2021)	Sphera SR MRI Surescan Class-D Shelf life: N/A Model: SPSR01	It is intended to generate and conduct electrical impulses to an abnormal heart to adjust its rate of contraction to meet the body's increased need for blood flow due to activity.	Approved.
79.	M/s Diag.M (Pvt) Ltd., B-270, Sector 6-F, EBM Causeway, Mehran Town, Korangi, Karachi (ELI-00184)	Legal Manufacturer: M/s BioSystems S.A. Costa Brava 30, Barcelona, Spain. FSC Spain Issuance Date (11-05-2018)	Bio Chemistry Control Serum Human I, II Class-B Shelf life: 30 months Codes & Sizes as per FSC 18042 (5x5ml), 18043 (5x5ml)	It is intended for quality control purposes only and is supplied with suggested intervals of acceptable values	Approved. Firm shall submit valid Letter of Authorization and ISO:13485.
80.	M/s Health Tec, House No. 10-B, Street 24, Valley	Legal Manufacture: SCW Medicath Ltd No. 4, Baolong 6 th road, Baolong Industrial Town,	SCW (Balloon Inflation Device) Class-B	Used to inflate and deflate an angioplasty balloon or other	Approved.

	Road, Westridge, 1 Rwp ELI: 000046	Longgang District Shenzhen, China FSC: China Date of Issue: 9 th July,2018 FSC Belgium issuance 12-08-2019	Shelf Life: 36 th Month Codes as per FSC	interventional device and to measure the pressure within the balloon.	
81.	M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi (ELI-00051)	Legal Manufacturer: Honsun (Nontong) Co., Ltd. Building 1, No. 8 Tongxing Road, Economic & Technological, Development Area, 226009 Nantong City, Peoples Republic of China. (FSC China Valid till 19-02-2022	ISOMED Aneroid Sphygmomanometer Class-B Shelf Life: Not Applicable. Codes as per FSC	Aneroid Sphygmoman ometer is a non- automated, mechanical blood-pressure monitor that used for the indirect measurement non-invasive) and display of arterial blood pressure.	Approved on the basis of CE mark documents.
82.	M/s Mehran Internation al 498/C Feroz Shah Mehta Road Karachi. (ELI- 00351)	Shandong yiguang medical instrument co., ltd, sanjiu science technology industrial park chiping county, shandong province p.r.china.	M.I. Dial Flow with Extension Tube Class: B. Claimed Shelf life: 05-years. Codes and sizes as per FSC	Dial Flow with Extension Tube	Approved on the basis of CE mark documents. Firm shall submit EPSPs.
83.	-do-	Changzhou kenno medical instrument co., ltd. No.2188 longcheng road, changzhou jinangsu, CHINA.	M.I. Three Way Stopcock Without Tube Class: B. Claimed Shelf life: 03-years. Codes and sizes as per FSC.	Three Way Stopcock Without Tube.	Approved. Firm shall provide FSC of China.
84.	-do-	Changzhou kenno medical instrument co., ltd. No.2188 longcheng road, changzhou	M.I. Three Way Stopcock with tube Class: B. Claimed Shelf life: 03-years-	Three Way Stopcock with tube.	Approved. Firm shall provide FSC of China.

		jinangsu, CHINA.	Codes and sizes as per FSC.		
85.	-do-	Shandong Qinkai Medical Industry Co., Ltd (The Southern Tip of Quancheng Road in Industrial Park, Chengwu, County, Heze City, Shandong Province P.R.China.	M.I. Scalp Vein Set Class: B Claimed Shelf life: 03-years. Codes and sizes as per FSC.	Scalp Vein Set used to puncture a vein , usually located in the individual's hands, wrists and/or scalp .	Approved.
86.	-do-	Shandong Qinkai Medical Industry Co., Ltd (The Southern Tip of Quancheng Road in Industrial Park, Chengwu, County, Heze City, Shandong Province P.R.China.	M.I. Blood Transfusion Set. Class: B. Claimed Shelf life: 03 years. Codes and sizes as per FSC.	Blood Transfusion Set used in medical operations for reliable blood or blood component transfusion and to prevent clot passage into the patient.	Approved.
87.	-do-	Shandong Qinkai Medical Industry Co., Ltd (The Southern Tip of Quancheng Road in Industrial Park, Chengwu, County, Heze City, Shandong Province P.R.China.	RELATION Dial Flow with extension tube Class: B. Claimed Shelf life: 05 years. Codes and sizes as per FSC.	Dial Flow with extension tube mainly used for regulating the flowing rate of infusing fluids when clinical infusion.	Deferred for submission / clarification of followings:- The firm shall submit original and valid FSC of country of origin i.e. China and RRA or CE certificates. Credential of manufacturer duly notarized.
88.	M/s.Medic amp	Legal Manufacturer:	Thermocut™ Forceps 10mm	THERMOC UT™	Deferred for

	International, Office no 1, First Floor, Raja Naseer Plaza, New Abadi, Morgah, Rawalpindi. (ELI-00200)	M/s. Lamidey Noury Medical 3 rue des petits ruisseaux, F-91370 Verrieres-Ie-Buisson, France FSC: FRANCE Date of issue: 07.02.2019	(Vessel Sealing Bipolar Forceps) Codes as per FSC. Class: C Claimed Shelf Life: 05 years	forceps is dedicated exclusively to vessel sealing (veins and arteries) up to 7mm vessel diameter, during open surgical procedures or laparoscopic surgical procedures, for the purpose of surgical removal of pathological tissue.	provision of following documents:- <ul style="list-style-type: none">• Valid ISO-13485 and QA certificate.• Manufacturing and QC details of the subject product.• Stability protocols as per claimed shelf life.• Mention MRP on application form.
89.	-do-	Legal Manufacturer: M/s. Lamidey Noury Medical 3 rue des petits ruisseaux, F-91370 Verrieres-Ie-Buisson, France FSC: FRANCE Date of issue: 22.10.2018	BIPOLAR Electrodes (Single use resection Electrode) Codes as per FSC Class: C Claimed Shelf Life: 05- years.	The Bipolar resection Electrodes are used for ablation and hemostasis of tissues under endoscopic control, in association with endoscopic accessories. They are intended for endoscopic surgeries with saline irrigation, in field of urology and gynecology.	Deferred for provision of following documents:- <ul style="list-style-type: none">• Valid ISO-13485 and QA certificate.• Manufacturing and QC details of the subject product.• Stability protocols as per claimed shelf life. Mention MRP on application

					form.
90.	-do-	<p>Legal Manufacturer: M/s. Lamidey Noury Medical 3 rue des petits ruisseaux, F-91370 Verrieres-Ie- Buisson, France. FSC: FRANCE Date of issue: 22.10.2018.</p>	<p>ELECTRO-Surgical Unit OPTIMA (High Requency Electro-surgical Units) Code: V10GOPT4 Class: C Claimed Shelf Life: 05 years</p>	<p>It is intended to be used for electro-surgical cutting and coagulation in monopolar and bipolar forceps for vessel sealing with THERMOC LAMP®, THERMOC UT® and THERMOCISION® forceps, and for bipolar resection in saline, with PALSMA EDGE ® electrodes.</p>	<p>Deferred for provision of following documents:-</p> <ul style="list-style-type: none"> • Valid ISO-13485 and QA certificate. • Manufacturing and QC details of the subject product. • Stability protocols as per claimed shelf life. <p>Mention MRP on application form.</p>
91.	M/s. Galaxy Pharma Pvt. Ltd, D-180, Rojhan Street, Block-5, Clifton, Karachi. (ELI: 00402)	<p>Legal Manufacturer: Lo Li. Pharma s.r.l. Via dei, Luxardo, 33-00156 Roma-Italy. Manufacturing Site: Nutralinea Srl, Via Gran Bretagna, 1-21013 Gallarate (VA) FSC: Italy Date of issue: 24.12.2019.</p>	<p>ALAPREG a-Lipoic acid (vaginal capsule) Class-B Claimed Shelf Life: 24 Months Codes as per FSC</p>	<p>a-Lipoic acid, vaginal capsule, an endogenous fatty acid acts as “scavengers” of free radical release and helps to normalize the inflammatory processes.</p>	<p>Approved. Firm shall submit valid ISO:13485 and EPSPs.</p>
92.	-do-	<p>Legal Manufacturer: Lo Li. Pharma s.r.l. Via dei, Luxardo, 33-00156 Roma-Italy.</p>	<p>SEMEVAG Vaginal ovules. Class- B Claimed Shelf life:</p>	<p>Vaginal ovules of Myo-Inositol at Ph 6, invasive device for</p>	<p>Approved. Firm shall submit valid ISO:13485 and EPSPs.</p>

		Manufacturing Site: Fluton Medicinali s.p.a via Marconi, 28/9-20020 Arese (MI) FSC: Italy Date of issue: 24.12.2019.	3 years Codes as per FSC	short term use. It increases and helps the chances of fertilization and pregnancy.	
93.	M/s. ASTO Life Sciences (Pvt) Ltd. Plaza No 1, Orchard 1 Block, Paragon City, BarkiRoad, Lahore. ELI-00103	Manufacturer: Becton, Dickinson and Company, BD Biosciences, 2350 QUME DR. San Jose, CA USA 95131 FSC Ireland valid till 21-12-2022	BD™ HLA-B27 Kit Code: 340183 Class-B Shelf Life: 6 months	Qualitative two-color direct immunofluorescence method for rapid detection of HLA-B27 antigen expression in erythrocyte-lysed whole blood using BD FACSCanto family of flow cytometers or the BD FACSCalibur, BD FACSort or BD FACScan flow cytometer	Approved.

Item No. IX. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A).

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad	Manufacturer: M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany. Manufacturing	Alinity s System Code: 06P16-01 Class A Shelf Life: N/A	Fully automated immunoassay analyzer designed to determine the presence of specific	Approved

	Road, Landhi, Karachi ELI-00019)	site: Abbott Laboratories 1921 Hurd Drive Irving, TX 75038, USA FSC Germany issued on 15-10-2018		antigens and antibodies by using chemiluminescent immunoassay technology	
2.	-do-	Manufacturer: M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany. FSC Germany Issuance Date 08-11-2017	Alinity hq Analyzer Class A Code: 09P68-01 Shelf Life: N/A	Quantitative multi-parameter automated hematology analyzer indicated for use to identify patients with hematologic parameters within and outside of established reference ranges	Approved. Firm shall submit separate application for Alinity h-series Water Purification System
3.	M/s. Asto Life Sciences (Pvt) Ltd, Plaza No 1, Orchard 1 Block, Paragon City, Barki Road, Lahore. ELI-00103	Manufacturer: Becton, Dickinson and Company, BD Biosciences, 2350 QUME DR. San Jose, CA USA 95131 FSC Ireland valid till 08-05-2023	BD FACSVia™ System (Flow cytometer) Code: 656874 Class: A Shelf Life: N/A	Identifies and enumerates leucocyte subsets for human cells in suspension	Approved. Firm shall submit label of code 656874 and Declaration of Conformity of this code
4.	M/s Global Marketing Services, 111, Hali Road Westridge-1, Rawalpindi ELI: 00109	Manufacturer: Xi'an Tianlong Science and Technology Co., Ltd No.389 Zhuhong Road, Xi'an, Shaanxi, 71008, P.R China FSC China valid	Gentier 96E (Real-Time PCR System) Class A Service life: 5 years	Intended for performing rapid, accurate polymerase chain reaction (PCR), meanwhile real-time measuring	Approved.

		till 19-03-2022		nucleic acid signals from DNA-binding fluorescent dyes or labeled probes and converts them to comparative quantitative readouts of DNA or reverse transcribed RNA.	
5.	M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061)	Legal Manufacturer: Medin Medical Innovations GmbH Adam-Geisler-Str.1 82140 Olching Deutschland/Germany (FSC Germany 13-09-2017)	Medin single use Bonnets Bonnets (single use) Class-A Shelf Life: 5 years Sizes: Bonnets REF: 1213-10, 1214-10, 1215-10, 1216-10, 1217-10, 1218-10, 1219-10, 1220-10	Miniflow® is a single use product for nCPAP therapy/ noninvasive ventilation therapy in treating neonates and premature infants in intensive care units. Can only be combined with the Medijet nCPAP generator.	Approved.
6.	M/s. ASTO Life Sciences (Pvt) Ltd. Plaza No 1, Orchard 1 Block, Paragon City, BarkiRoad, Lahore. ELI-00103	Legal Manufacturer: Becton, Dickinson & CO. 1 Becton Drive, Franklin Lakes, NJ 07417 USA Manufacturing site: Becton, Dickinson &	BD Microtainer® MAP Microtube for automated Process K2 EDTA 1.0 mg (Blood Collection Tube) Code: 363706	Non-sterile, single use tube used to collect, transport and store skin puncture blood specimens for the hematology tests or for	Approved. Firm shall provide stability studies for claimed shelf life of 18 months.

		CO. 150 S 1 st Ave, Broken Bow, NE USA 68822	Class A Shelf Life: 18 Months	test utilizing serum or heparinized plasma.	
		FSC USFDA valid till 10-09- 2021			

Item No.X. DEFERRED CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Following applications for registration of Medical Devices for import were placed before the MDB in its different meetings and deferred for provision of documents. Now the firm has submitted documents

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Decision
1.	M/s Ghazali Brothers, 1st Floor, Azzainab Court Campbell Street, Karachi (ELI-00240)	Legal Manufacturer: Ningbo Yingmed Medical Instruments Co., Ltd. Uingsheng Building No. 456 Tai'an Road, Southern Business Zone, 315199, Ningbo, China. FSC MHRA issuance 09-02-2018	YINGMED SAFETY SYRINGE (AUTODISABLE) STERILE Class-B Shelf life: 05 years Codes and sizes as per FSC 2ml, 3ml, 5ml, 10ml, 20ml	Used in human body hypodermic injection and solution aspiration.	Approved.
2.	M/s Hashir Surgical Services, Office No. 16, Street 1, F-2, Phase 6, Hayatabad, Peshawar Office No. 05, 2nd Floor, Syed's Tower, University Road, Peshawar House No. 2, Street No, 1, Gulshan	Legal Manufacturer: M/s Shanghai Dassheng Health Products Manufacturing Co., Ltd, No. 228 Shihui Road, Songjina, Shanghai, P.R. China. FSC China issuance 22-04-2021 valid for	DASHENG (N95 Surgical Mask) Class-A Shelf life: 3 years Codes/ models: DTC 3M-1, DTC3B	The N95 Surgical Masks are intended for Single Use by operating room personnel and other healthcare workers to protect both the patients and healthcare workers from transfers of microorganism,	Approved.

	Colony, GT, Road, Peshawar ELI: 00075	two years		blood and body fluids, virus, pathogens, bacteria and airborne particulate materials.	
3.	M/s. Cardiac Care, 848-C, Shadman-I Lahore. ELI-00070	Legal Manufacturer: M/s KOO Medical Equipment Co. Ltd., 100 Zhongde Road, Xiaokunshan Town, songjiang, Shanghai 201614, P.R. China	Anesthesia Mask Class: B Shelf life: 5 years Codes as per FSC	Anesthesia Mask	Approved.
4.	M/s Meher Traders, Office No. A-21-22 First Floor Zeenat Medecine Market North Nappier Road, Karachi. (ELI-00128)	Legal Manufacturer: Hunan Luzhou Huikang Development Co., Ltd Located at No. 122 Luzhou Road, Suining County 422600 Hunan China. FSC China validity 13-11- 2021	Wellmed IV Burette IV Burette Class B Shelf Life: 5 Years Sizes & Codes as per FSC	Sterile IV Burette for single use	Approved.
5.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156.	Legal Manufacturer: 3 Boulevard Raymond Poincare, 92430 Marnes-la- Conquette, France. FSC: France	PLATELIA SARS-CoV-2 Total Ab Assay Kit to screen for total anti- nucleocapsid antibodies (IgM, IgA, IgG) to coronavirus SARS-Cov-2. Class-C Shelf Life: 12 months.	Provided free sale certificate (FSC) doesn't contains the name or annex. of the product applied. Provide the original & valid agency agreement with all coded particulars as per MDB-06.	Approved.

Item No.XI. APPROVED SUBJECT TO CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Reasons for Conditional Approval
1.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	Legal Manufacturer/ Manufacturing Site: M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea. (FSC Korea Dated 11-08-2017)	SD BIOLINE Dengue IgG/IgM Test Kit Class C (1)SD BIOLINE Dengue IgG/IgM 11FK10 (25 Test/Kit) Shelf Life: 24 Months	It is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to dengue virus in human serum or plasma	Approved in 12 th MDB meeting subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.
2.	-do-	Legal Manufacturer/ Manufacturing Site: M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea. (FSC Korea Dated 11-08-2017)	SD BIOLINE TB Ag MPT64 Rapid Test Kit Class C (1)SD BIOLINE TB Ag MPT64 Rapid 08FK50 (25 Test/Kit) Shelf Life: 18 Months	It is a rapid immunochromatographic identification test for the M. tuberculosis complex that uses mouse monoclonal anti-MPT64.	Approved in 12 th MDB meeting subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.
3.	-do-	Legal Manufacturer/ Manufacturing Site: M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si,	SD BIOLINE Dengue IgG/IgM, WB Test Kit Class C (1)SD BIOLINE Dengue IgG/IgM, WB 11FK20 (25 Test/Kit) Shelf Life: 24 Months	It is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to dengue virus in human serum, plasma or whole blood.	Approved in 12 th MDB meeting subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant

		Gyeonggi-do, Republic of Korea. (FSC Korea Dated 11-08-2017)			is approved by the panel of experts.
4.	-do-	Legal Manufacturer/ Manufacturing Site: M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea. (FSC Korea Dated 11-08-2017)	SD BIOLINE Syphilis 3.0 Test Kit Class C (1)SD BIOLINE Syphilis 3.0 06FK10 (30 Test/Kit) (2)SD BIOLINE Syphilis 3.0 06FK11 (Multi) (100 Test/Kit) Shelf Life: 24 Months	It is a solid phase immunochromatograph ic assay for the qualitative detection of antibodies of all isotypes (IgG, IgM, IgA) against Treponema pallidum. This test is used as an aid on the diagnosis of syphilis.	Approved in 12 th MDB meeting subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.
5.	-do-	Legal Manufacturer/ Manufacturing Site: M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea. (FSC Korea Dated 11-08-2017)	SD BIOLINE Dengue Duo Test Kit Class C (1)SD BIOLINE Dengue Duo 11FK45 (10 Test/Kit) (2) SD BIOLINE Dengue Duo 11FK46 (25 Test/Kit) Shelf Life: 24 Months	It is an in vitro immunochromatograph ic, one step assay designed to detect dengue virus NS1 antigen, IgG and IgM antibodies to dengue virus in human serum, plasma or whole blood.	Approved in 12 th MDB meeting subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.
6.	-do-	Legal Manufacturer/ Manufacturing Site: M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.	SD BIOLINE Dengue NS1 Ag Test Kit Class C (1)SD BIOLINE Dengue NS1 Ag 11FK50 (25 Test/Kit) Shelf Life: 24 Months	It is an in vitro immunochromatograph ic, one step assay designed to detect dengue virus NS1 antigen in human serum, plasma or whole blood.	Approved in 12 th MDB meeting subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.

		(FSC Korea Dated 11-08-2017)			
7.	-do-	<p>Legal Manufacturer:</p> <p>Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea</p> <p>Manufacturing Site:</p> <p>Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea</p> <p>(FSC Korea issue 11-08-2017)</p>	<p>SD BIOLINE Influenza Ag A/B/A (H1N1) Pandemic</p> <p>19FK31 (10 tests/kit) & 19FK32 (25tests / Kit)</p> <p>Class-C</p> <p>Shelf Life 24 Months.</p>	<p>It is a chromatographic immunoassay for the differential and qualitative detection of Influenza virus type A, type B and A(H1N1) Pandemic antigens directly from nasal/throat / nasopharyngeal swab or nasal/nasopharyngeal aspirate specimens.</p>	<p>In MDB 13th the Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.</p>
8.	-do-	<p>Legal Manufacturer:</p> <p>Standard Diagnostics, Inc. 65, Borahaga I-ro, Giheung-gu, Yongin-si, Gyeonoggi-do, Korea.</p> <p>Manufacturing Site:</p> <p>Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea</p> <p>(FSC Korea Issuance 11-03-2019)</p>	<p>SD Bioline Salmonella Typhi IgG/IgM Fast</p> <p>SD Bioline Salmonella Typhi IgG/IgM Fast</p> <p>Class C</p> <p>Shelf Life: 24 Months</p>	<p>It is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to Salmonella typhi in human serum, plasma or whole blood</p>	<p>In MDB 13th the Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.</p>

9.	-do-	<p>Legal Manufacturer: Standard Diagnostics, Inc. 65, Borahaga I-ro, Giheung-gu, Yongin-si, Gyenoggi-do, Korea.</p> <p>Manufacturing Site: Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea</p> <p>(FSC Korea Issuance 11-03- 2019)</p>	<p>Panbio Dengue Early Rapid</p> <p>Class C</p> <p>Shelf Life: 24 Months</p> <p>Panbio Dengue Early Rapid 01PF20</p>	<p>It is an in vitro immunochromatographic, one step assay designed for the qualitative determination of dengue virus NS1 antigen in human serum, plasma or whole blood for the diagnosis of early acute dengue infection</p>	<p>In MDB 13th the Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.</p>
10.	-do-	<p>Legal Manufacturer: Standard Diagnostics, Inc. 65, Borahaga I-ro, Giheung-gu, Yongin-si, Gyenoggi-do, Korea.</p> <p>Manufacturing Site: Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea</p> <p>(FSC Korea Issuance 11-03- 2019)</p>	<p>Panbio Dengue IgM Capture ELISA</p> <p>Class C</p> <p>Shelf Life: 15 Months</p> <p>Panbio Dengue IgM Capture ELISA 01PE20</p>	<p>It is for the qualitative detection of IgM antibodies to dengue antigen in serum, as an aid in the clinical laboratory diagnosis of patients with clinical symptoms consistent with dengue fever</p>	<p>In MDB 13th the Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.</p>
11.	-do-	<p>Legal Manufacturer: Standard Diagnostics, Inc. 65, Borahaga I-ro, Giheung-gu,</p>	<p>SD Dengue IgM Capture ELISA</p> <p>Class C</p>	<p>It is an enzyme-linked immunosorbent assay for the qualitative detection of IgM antibodies specific to Dengue virus in human</p>	<p>In MDB 13th the Board deliberated the Export only certificate at length and considering that product fulfills the</p>

	Yongin-si, Gyenggi-do, Korea. Manufacturing Site: Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea (FSC Korea Issuance 11-03- 2019)	Shelf Life: 18 Months SD Dengue IgM Caputure ELISA	serum.	range of products required to be registered and approved the product subject to inspection abroad.
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Decision: The Board approved the products at S.No 1-11 on the basis of Free Sale Certificate of Germany and with the new name of manufacturer and products as mentioned above.

Item No.XII. CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT (COVID RELATED).

S. #	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Decision
1.	Zenith International, Room No.104, Tahir Plaza, A/20, Block 7 & 8 KCHSU, Karachi (ELI-00090)	Manufacturer: M/s GMP Medicare SDN. BHD., F25, Lot/Pt 64593, Jalan Dahlia/KU8, Kawasan Perindustrian Meru Timur, 41050 Klang, Selangor, Malaysia. FSC Malaysia valid till 03-02-2023	PERFECT Nitrile Examination Gloves (Powder Free) Sizes: Small, Medium, Large, Extra Large Class A Shelf life: 5 years	Nitrile Examination Gloves made from synthetic rubber latex, Non-Sterile, Powder Free, Single use	Approved.
2.	-do-	Manufacturer: M/s GMP Medicare SDN. BHD., F33, Lot	PERFECT Latex Examination Gloves (Powder	Latex Examination Gloves made from natural	Approved.

		3276, Kawasan Perindustrian Nilai, Mukim Sentul, Daerah Seremban, 71800 Nilai Negeri Sembilan, Malaysia. FSC Malaysia valid till 03-02-2023	Free) Sizes: Small, Medium, Large, Extra Large Class A Shelf life: 5 years	rubber latex, Non-Sterile, Powder Free, Single use	
3.	-do-	Manufacturer: M/s Blue Sail Medical Co., Ltd No. 21 Qingtian Road, Qilu Chemical Industrial Park, Zibo City, Shandong Province, China FSC China valid till 7-6-2022	PERFECT Vinyl Examination Gloves (Powder Free) Sizes: Small, Medium, Large, Class A Shelf life: 5 years	Vinyl Examination Gloves made with PVC, Non-Sterile, Powder Free, Single use	Approved.
4.	M/s SY'AH Impex, 1-6/15 Sector 5 Korangi Industrial Area, Karachi. ELI-00440	Manufacturer: Shanghai Motex Healthcare Co., Ltd No. 369, Jiasong Zhong Rd., Huaxin, Qingpu, Shanghai 201708, P. R. China. FSC of China valid till 27 th June 2021	Shifa Gynae Surgical Gloves (Powder free) Sizes: S, M, L Class: B Code: 1310 Shelf life: 3 years	Made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination Sterile, single use	Approved.
5.	-do- -	Manufacturer: Shanghai Motex Healthcare Co., Ltd No. 369, Jiasong Zhong Rd., Huaxin, Qingpu, Shanghai 201708, P. R.	Shifa Orthopaedic Surgical Gloves (Powder free) Sizes: 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 Class: B	Made of natural rubber intended to be worn by operating room personnel to protect a	Approved.

		China. FSC of China valid till 27 th June 2021	Code: 1810 Shelf life: 3 years	surgical wound from contamination Sterile, single use	
6.	-do-	Manufacturer: Shanghai Motex Healthcare Co., Ltd No. 369, Jiasong Zhong Rd., Huaxin, Qingpu, Shanghai 201708, P. R. China. FSC of China valid till 27 th June 2021	Shifa Surgical gloves (Latex Powder free) (6.0, 6.5, 7.0, 7.5. 8.0, 8.5) Class-B Shelf life: 3 years Fee submitted: Rs. 25,000/-	Sterile disposable device made of natural rubber latex and intended to be worn on hands, usually in surgical setting, to provide barrier against potentially infectious material and other contaminants . Single use	Approved.
7.	M/s Global Marketing Services, 111, Hali Road Westridge-1, Rawalpindi ELI: 00109	Legal Manufacturer: M/s Cepheid, 904 Caribbean Drive Sunnyvale, CA, 94089, USA Manufacturing sites: 1. M/s Cepheid, 904 Caribbean Drive Sunnyvale, CA, 94089, USA 2. M/s Cepheid AB Rontgenvagen 5, SE-171 54 Solna, Sweden FSC France issued on 16.12.2020	Xpert® Xpress SARS-CoV-2 (Kit) (real time RT PCR kit) Code: XPRSARS-COV2-10 Class C Shelf Life: 12 months	A real time RT PCR test kit for use with GeneXpert Dx or GeneXpert Infinity Systems. Intended for qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swab, nasal swab, or nasal wash/aspirate specimen collected from individuals who are	Approved.

				<p>suspected of COVID-19 infection. Result are for identification of SARS-CoV-2 RNA. Negative results do not preclude SARS-CoV-2 infection and should not be used as sole basis for treatment or other patient management decisions</p>	
8.	<p>M/s Nisa Impex (Pvt) Ltd, Plot no. 13-14, Usman Block, Jeddah Town, Phase-1, Opp. DHA-II G.T. Road Islamabad. ELI-00064</p>	<p>Manufacturer: Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co., Ltd. No. 46, 7th Group, Wanjie Village, Xinping Town Xinjin County, Chengdu, P.R China. FSC China valid till 11-1-2023</p>	<p>Nisa Medical Protective Face Mask FHZ-2 Class A Shelf life: 2 years</p>	<p>Used for filtering particles, blocking droplets, blood, bodily fluids and secretions in the air under the medical working environment . Sterile, single use</p>	Approved.
9.	-do-	<p>Manufacturer: Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co., Ltd. No. 46, 7th Group, Wanjie Village, Xinping Town Xinjin County, Chengdu, P.R</p>	<p>Nisa Surgical Face Mask Codes: as per FSC China No. 20200024 Class A Shelf life: 2 years</p>	<p>For clinical medical personnel to wear in the process of traumatic operation to provide protection for the patients who are being treated and</p>	Approved.

		China. FSC China valid till 26-3-2022		medical staff and prevent spread sored of blood, body fluids and splashes. Single use	
10.	-do-	Manufacturer: Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co., Ltd. No. 46, 7 th Group, Wanjie Village, Xinping Town Xinjin County, Chengdu, P.R China. FSC China valid till 26-3-2022	Nisa Medical Face Mask Codes: KZ-4J-WJ, KZ-8J-WJ, KZ-4J-FWJ, KZ-8J-FWJ Class A Shelf life: 2 years	Suitable for health care in normal environment . Single use	Approved.
11.	M/S B.N Trading Company Office No 207, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar, KPK ELI: 00647	<u>Legal Manufacturer:</u> Hubei Feiteng protective Products Co., Ltd No. 72 Shahu Avenue Shahu Town Xiantao City Hubei Province China FSC: China (CCIE&HP) Date of issue: 2.02.2021	Disposable Face Mask Class-A Shelf life: Models: Ft-I, FT-II, FT- III	Disposable face mask	Deferred for provision of following documents:- <ul style="list-style-type: none"> • Brand name of the device applied. • FSC in the country of origin issued by China FDA duly attested by Embassy of Pakistan, the provided FSC is issued by China Chamber of commerce for import & export of Medicines &

					<p>health products.</p> <ul style="list-style-type: none"> • CE marked document, duly notarized. • Shelf life studies, shelf life is not mentioned. • Labels of applied codes/sizes as per FSC, approved in the country of origin.
12.	<p>M/s Aqib Trading Company (Pvt) Ltd, Main G.T Road, Adamzai, Akora Khattak Nowshera KPK</p> <p>ELI-00628</p>	<p><u>Manufacturer</u> : Jiangxi Hongda Medical Equipment Group Ltd 39 South Shengli Road, Jinxian Country, Nanchang City Jiangxi Province, China</p> <p>FSC China issued by administrative Examination and Approval Bureau of Nan Chang valid till 2022.11.05</p>	<p>AT-TEX single use sterile rubber surgical gloves (powder free)</p> <p>Sizes: 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5</p> <p>Class B</p> <p>Shelf Life: 5 years</p>	<p>Surgical gloves made from natural rubber latex, powder free. Sterile, Single use</p>	<p>Approved.</p>

Item No.XIII. REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 7)

Sr. No.	Name & Address of Establishment	Name of Medical Devices With	Brief Description	Decision
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		Size		
1.	M/s Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014)	Sodium fusidate Gauze Dressing BP-1988 (Fusitin Tulle) Shelf life 05 years. Class C Rs.20,000/- Sizes as Applied.	Used for wound infectionsulcresburns etc.	Deferred for product specific inspection.
2.	-do-	Chlorohexidine Tulle B.P-1988 (Septi Grass Tulle) Shelf life 05 years. Class C Rs.20,000/- Codes & Sizes as per Applied.	Used as a primary wound contact layer in TheTreatmentOf wound Infections	Deferred for product specific inspection.
3.	M/s 3N-Lifemed Pharmaceuticals, 45 SB Abdullah Colony, Sargodha (ELM-0026)	Lifemed Sodium Hypochloride 5%-10% (3NLSHS) 5 Liter Shelf life 03 years. Class C Rs.20,000/- Codes & Sizes as per Applied	Sodium Hypochloride 5%-10%	Approved. Firm shall provide stability data for claimed shelf life and documents for manufacturing and quality control process.
4.	-do-	Lifemed Activated Charcoal (3NLAC) 25g, 500g Shelf life 03 years. Class C	Activated Charcoal	Approved. Firm shall provide stability data for claimed shelf life and documents for manufacturing and quality control process.

		Rs.20,000/- Codes & Sizes as per Applied		
5.	-do-	Lifemed Citro Cath (3NLCC) 3ml, 5ml Shelf life 03 years. Class C Rs.20,000/- Codes & Sizes as per Applied	Trisodium Citrate / Ethanol	Approved. Firm shall provide stability data for claimed shelf life and documents for manufacturing and quality control process.
6.	-do-	Lifemed Hydrochloric Acid (3NLHCLS) 2..5Liter, 5Liter Shelf life 03 years. Class C Rs.20,000/- Codes & Sizes as per Applied	Hydrochloric Acid 5-30%	Approved. Firm shall provide stability data for claimed shelf life and documents for manufacturing and quality control process.

Item No.XIV. REGISTRATION OF RENEWAL OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 7)

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	Paktex Industries, 2.5 K.M. Tatlay Road, Sroya abad, Kamoke Gujranwala (ELM-0025)	Pak Band X Rays Detectable Abdominal/LAP Sponges/PADS/Guaze BP Shelf life: 02 Years Class C	An X-ray detectable Lap Sponges consists of absorbent cotton gauze which is folded in such a manner that no cut edges are	Deferred for provision of stability data for claimed shelf life and product specific inspection.

		Sizes & Codes as already registered 22.5cm x22.5cm 4Ply, 6Ply 30cm x 30cm 4Ply, 6Ply 45cm x 45cm 4Ply, 6Ply	exposed and stitches round the open sides.	
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Item No.XV. ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	M/s Paktex Industries, 2.5 K.M. Tatlay Road, Sroya abad, Kamoke Gujranwala (ELM-00025)	Propore Surgical Paper Tape Bandages (Non-Woven Surgical Paper Tape Bandages/Dressing 12mm x 4.5m, 12 Rolls Per Box 20mm x 4.5m, 12 Rolls Per Box 25mm x 4.5m, 12 Rolls Per Box 50mm x 4.5m, 12 Rolls Per Box 75mm x 4.5m, 12 Rolls Per Box 100mm x 4.5m, 12 Rolls Per Box 12mm x 3.0m, 12 Rolls Per Box 20mm x 3.0m, 12 Rolls Per Box 25mm x 3.0m, 12 Rolls Per Box 50mm x 3.0m, 12 Rolls Per Box 75mm x 3.0m, 12 Rolls Per Box 100mm x 3.0m, 12 Rolls Per Box 12mm, 20mm, 25mm, 50mm,	it is used to fixing injection needles, surgical cotton gauze, bandages and for catheters and tubes.	Approved.

		75mm, 100mm, width wise & 3mtrs, 4mtrs, 4.5mtrs, 5mtrs, 6mtrs, 7mtrs, 8mtrs, 9mtrs, 10mtrs Length wise Class A Shelf Life: 05 Years Rs.5000/-		
2.	M/s Pharmatec Pakistan (Pvt) Ltd., D-86/A, SITE, Karachi (ELM-0035)	Exo Cream 50gm, 125gm, 350gm, 500gm Class A Shelf Life: N/A Rs.5000/-	it is formulated to provide relief in pruritic and dry skin.	Deferred for provision of evidence that applied product is a medical devices.
3.	-do-	Hypobase Gel 100gm, 500gm Class A Shelf Life: N/A Rs.5000/-	it is formulated to provide relief in pruritic and dry skin.	Deferred for provision of evidence that applied product is a medical devices.

Item No.XVI. APPLICATIONS FOR RENEWAL OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	Paktex Industries, 2.5 K.M. Tatlay Road, Sroya abad, Kamoke Gujranwala (ELM-0025)	Open Wove Bandages BPC 2.5cm x 1m x 12 Shelf life: 03 Years Class A Sizes & Codes as already registered	It is used to protect dressing and hold them in place and to give support. It is also used to secure splints	Approved.

2.	-do-	<p>Sera Tulle (Sterile) Contains:- Chlorhexidine Acetate0.5% w/w Ointment Base (Paktex's Specs)</p> <p>Shelf life: 03 Years</p> <p>Class A</p> <p>5cm x 5cm 1's (Single Sheet) 10cm x 10cm x 1's (Single Sheet) 12.5cm x12.5cm x 1's (Single Sheet) 15cm x 15cm x 1's (Single Sheet) 15cm x 10cm x 1's (Single Sheet) 20cm x 20cm x 1's (Single Sheet)</p> <p>Sizes & Codes as already registered</p>	<p>Gauze cloth impregnated with white soft paraffine use for burns and scars</p>	<p>Deferred for product specific inspection, provision of stability data for claimed shelf life and differential fee of Rs,5000/-.</p>
3.	<p>M/s Hafiz Pharma Industry, Neelam Cinema Road, Kamoke (ELM-0012)</p>	<p>Surgeon Cotton Crepe Bandage BPC 15cm x 4.5m 10cm x 4.5m 7.5cm x 4.5m 15cm x 3m 10cm x 3m 7.5cm x 3m</p> <p>Shelf life: 03 Years</p> <p>Class A</p> <p>Sizes & Codes as already registered</p>	<p>Surgeon Cotton Crepe Bandage BPC it is used for dressing</p>	<p>Approved.</p>

Item No.XVII. SUBMISSION OF FREE SALE CERTIFICATE OR CE MARKED DOCUMENTS BY IMPORTERS.

The case of the M/s Care and Cure International, 65-B, Satellite Town Rahim Yar Khan for the below medical device was considered by the MDB in its 14th meeting held 11-10-2019 and approved subject to inspection of manufacturer abroad:-

1.	M/s. Care and Cure International. 65-B, Satellite Town Rahim Yar Khan. ELI-00192	Legal Manufacturer & Manufacturing Site: M/s Yangzhou Goldenwell Medical Devices, No. 16 Tengfei Road, Dinggou Industrial Park of Jiangdu District, Yangzhou city, Jiangsu Province, P.R. China. FSC China 08-01-2021	Cure (Disposable Syringe) Class B Shelf Life: 05 years Disposable Syringe with needle (1, 3, 5, 10, 20, 30 and 50ml) Rs.25,000/-	Disposable Syringe	Approved subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017.
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Decision: The Board approved the above mentioned product on the basis of CE mark documents submitted by the firm.

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